Tampere University

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DEVELOPMENT OF PRODUCTIZED SERVICE LIFE CYCLE MODEL FOR MEDICAL DEVICES

A case study

Faculty of Medicine and
Health Technology

Master of Science Thesis

September, 2019

ABSTRACT

Iikka Luosa: Development of productized service life cycle model for medical devices

Master of Science Thesis

Tampere University

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Developing a functional service portfolio around a product is vital for a manufacturer to flourish. Today technology companies are expected not only to provide top quality products but the appropriate service packages around them too. Serres Oy is a Finnish company operating globally in theatre liquid management business. They have claimed a Europe leading market share with their high-quality single-use products. Now the company is developing progressive solutions for waste management in hospital environment. The solutions revolve around smart liquid waste management and automatic collection of operation theatre liquids. These devices have been under development for years, and now with the expansion to the medical device manufacturing, the company strives to chart the customer service needs and culture. For this reason, the study is aimed to map the customer needs and to create a basic model proposition for services around medical devices.

This study was conducted as an insider action research. There were 23 interviews from all levels of the service chain. The interviewees were selected from within the case company, from its contracted service organisations, and from customers' service organisations. The pre-determined theme lists guided the semi-structured interviews while allowing some room for the discussion to flow naturally. The themes were set with a guiding group inside the case company. The goal was to provide valuable information from both the company's own personnel as well as the technology experts along the service chain. Later the research findings were combined with theoretical background knowledge to provide a well-grounded development proposal in form of a productized service life cycle model.

Theoretical background provided an extensive base to build research results on. The interview results are condensed to figures of simplified business environment and a figure depicting essential services. These results are further refined into proposals of service blueprint models in the phases of a medical device life cycle. The phases were identified during the research: sales, warranty, use, and recycling. These service models are accompanied with proposals of product-service system inclusion concept as well as a rationalized pricing method proposal. It is inevitable, that the future of service also in the medical field must apply the internet connection through a value creating method. Thus, it is recommended continuing the research towards an application of remote defect diagnosis tool for medical devices.

Keywords: Life cycle, Service, Medical device, Model

TIIVISTELMÄ

Iikka Luosa: Tuotteistettujen palveluiden elinkaarimallin kehittäminen lääkinnällisille laitteille

Diplomityö

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Toimivan palvelu- ja huoltoportfolion rakentaminen tuotteen ympärille on elintärkeää yritykselle. Nykyaikana yritysten odotetaan tarjoavan laadukkaiden tuotteiden lisäksi niihin liittyviä tukitoimintoja. Serres Oy on suomalainen perheyritys, joka erikoisalaa on leikkaussalien nesteidenkäsittely. Se on saavuttanut Euroopan markkinajohtajan aseman laadukkailla kertakäyttötuotteillaan ja nyt tavoitteena on kehittää edistyksellisiä sekä älykkäitä automatisoituja laitteita nesteidenkäsittelyn tueksi. Kehitystyötä on tehty vuosia ja nyt kun yritys siirtyy laitemarkkinoille, on tarve kartoittaa asiakkaiden odotuksia ja vaatimuksia palveluiden ja huollon kannalta. Tästä syystä tämä diplomityö pyrkii luomaan esityksen huollon ja palveluiden perusmallista lääkinnällisten laitteiden ympärille.

Tämä tutkimus suoritettiin toimintatutkimuksena. Haastatteluja tutkimuksen aikana suoritettiin 23. Haastatteluihin lukeutui keskusteluja kohdeyrityksen omien huoltoammattilaisten kanssa, suomalaisten asiakkaiden teknisen henkilökunnan kanssa, saksalaisen huoltokumppanin erikoisosaajien sekä saksalaisten asiakkaiden teknisen henkilökunnan kanssa. Nämä puolistrukturoidut haastattelut noudattivat ennalta määritettyjä teemoja jättäen kuitenkin tilaa keskustelunomaiselle etenemiselle. Teemat määriteltiin kohdeyrityksen ohjausryhmän kanssa siten, että tietoa saatiin kerättyä sekä omilta työntekijöiltä että asiakkaiden osaajilta. Myöhemmin haastatteluista kerätty informaatio yhdistettiin teoreettiseen taustatietoon, jotta voitiin luoda perusteltu esitys huollon elinkaarimallista lääkinnällisille laitteille.

Teoreettinen taustatieto tarjoaa kattavan pohjan tutkimusosuuden tuloksille. Haastattelujen tulokset on tiivistetty kuvaajiin yksinkertaistetusta liiketoimintaympäristöstä sekä kuvaajaan lääkinnällisten laitteiden palvelu- ja huoltotoiminnan keskeisistä osista. Näistä tuloksista jalostettiin ehdotelmat tutkimuksen aikana selkeytyneihin elinkaaren vaiheisiin jakautuvat service blueprint -mallit. Näitä malleja täydentävät tuotepalvelusysteemin sisältöjen tasoehdotelma sekä perusteltu näkemys hinnoittelun uudistamisen mahdollisuuksista. On väistämätöntä, että myös lääkinnällisten laitteiden huollon tarvitsee tulevaisuudessa hyödyntää internet-yhteyttä arvoa luovalla tavalla. Täten tämän diplomityön perusteella suositellaan jatkettavan tutkimus- ja kehityshanketta kohti laitteiden etädiagnosointiin käytettävää verkkotyökalua sisältäen sen mahdollisuudet ja rajoitukset.

Avainsanat: Elinkaari, Palvelut, Huolto, Lääkinnällinen laite, Malli

PREFACE

Thesis work demonstrates the graduate's eligibility for graduation and reflects their maturity and growth during the path of education. After a remarkable personal process, I certainly am convinced of the Finnish educational system and I have to admire the everyday effort people provide in behalf of the society.

I would like to express my gratitude to all the people I have met on my path to this degree. You have influenced my work and my personality with your actions, and I am sure those actions will continue to guide my way for a long time. Especially I would like to thank my closest family. You supported me in moments of doubt and hardship, when one needs the support most but doesn't apprehend to ask for it or to thank you for it. Additionally, I want to express my gratitude for my friends. For the longest time, you were the sole reason to bring myself to the halls of education, or at least to the school premises. Every moment spent with you will bring a smile to my face for years to come. And last, but not least, I would like to thank Serres Oy and my friends there, for giving me a chance to a meaningful and interesting thesis as well as for providing me both an excellent environment to work in and a vision for the future.

Thank you.

Iikka Luosa

Tampere, 13th of September 2019

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LIST OF ABBREVIATIONS

CFDA	China Food and Drug Administration
CRM	Customer Relationship Management
EU	European Union
FDA	Food and Drug Administration
LCC	Life Cycle Cost
LCM	Life Cycle Management
PSS	Product-service system
R&D	Research and development
TAU	Tampere University

1. INTRODUCTION

Providing customers with well performing products is a life cycle process. Technology and market sense are in the centre of value during life cycles in terms of customers, products and services. Developing and providing only a product does not fill the customer needs as today companies are expected to present valuable service around their products. When services are combined with actual products, they form a more flexible and more appealing portfolio with a possibility of productizing services. Productization provides the company a way to serve more extensive and variable net of customers without increasing the organisational load over its capacity.

This master's thesis has been conducted as an assignment from Serres Oy, the case company. Since Serres Oy is a producer in a special and narrow market segment, they strive to be consistent in their actions. As a market leader they also must be progressive to maintain this status. It is a challenging balance. As a company Serres has built a brand of quality and reliability and intends to maintain this while moving into international medical device markets. This expansion requires a credible service portfolio to be sustained. However, the portfolio created in this thesis is left in the state of a theoretical proposal without actual plan for execution.

In the faculty of Medical Sciences and Biotechnology this thesis stands out with the strong nuances of industrial management. The usual nature of said faculty's master's theses are of technical research inside Tampere University (TAU) and because of the focus on interviews this thesis requires slightly different state of mind. This thesis is especially demanding since assimilating the unity requires technical expertise as well as business vision.

1.1 Thesis objectives

The objective for this thesis is to provide information and propose a basic model of productized service life cycle for medical devices. Additionally, the case company is in a central role when creating the results. As Serres Oy operates internationally and is expanding the product portfolio into the realm of medical devices, it is vitally important to provide adequate service. Service is a broad definition and here we are concentrating

on consumable maintenance and device implementation. In this case study the main goal is to find out the essential elements for medical device service. As the research output is combined with appropriate background information, this study aims to propose a service life cycle model for the case company's products. These goals provided a practical base to build the thesis, although the final form of the objectives was finetuned during the process. The composition of the goal is visualised in figure 1.

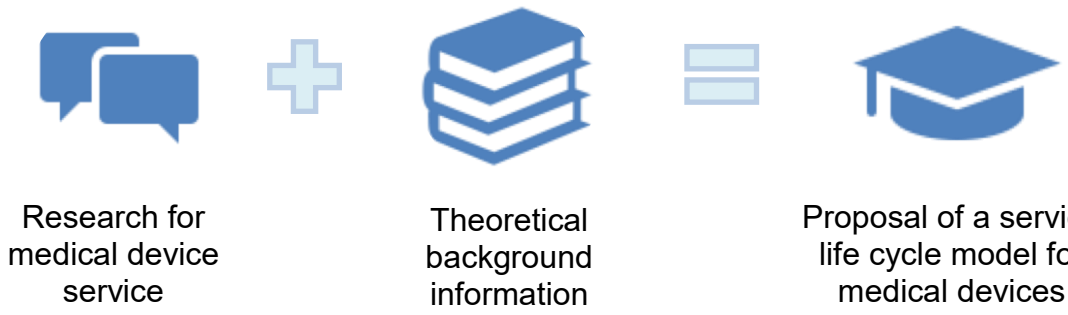

Figure 1. *Thesis objective composition*

As the figure 1 indicates, the thesis objective is built of both research interviews and research of background information. Thus, the result of this thesis is based both on theoretical scientific literature and research. Naturally this thesis is created to accompany the vast information pool of scientific community while still setting the priority to be the creation of knowledge to further the case company agenda.

1.2 Research approach and methods

Since the thesis was created as a task from the case company, it is only natural for the researcher to work as a member of the company. This provided the researcher the accreditation to use the information technology and communication tools as well as contact customers and their experts. All of these were utilized in order to gather information from inside the company's organization and from the customer point of view. The mentioned two points of vision are used to understand the duality of service and experience.

As Saunders *et al.* (2009, p.106-136) describes different research approaches, this study is conducted with inductive approach. In essence this means, that compared to

deductive research where a theory is tested with research, with inductive research a theory emerges from the research results. The research approach resembles closely an approach called **insider action research**. In insider action research a member or a team of members of organization are working towards improvement of sustained learning while developing the system (Reason *et al.* 2001, p. 643-644).

The research is based on discussions and guidance from both faculty and company sides and insider action research was seen to pursue the goals most extensively. This method has been widely used in similar types of thesis studies. The actual method is described in more detail in the research method chapter.

1.3 Study process

The thesis process really began in March 2019 with schedule planning for the whole process, which was to end in October 2019. The project ended ahead of schedule in September. Initially discussions of thesis process were already had during summer 2018 in small glimpses. The first three months from March till May were agreed to be worked under a part time contract of maximum two days a week. From June 2019 onwards the thesis work would continue as full time with minimal support to ongoing projects in the company.

Generally, the schedule was divided into three major parts: conducting research, writing background information and analysing the results. Even though the order was a bit unorthodox, this is not unheard of. The research was set to be conducted first during spring months to avoid the summer vacation period of interview subjects and thus to maximise the number of results. This created challenges for researcher to comprehend the necessary background information and to conduct said research in a rapid pace. Gantt-figure was used to support the management of resources, time and progress of the process, shown in figure 2. This figure is also presented in appendix A, since the difference in physical sizes for the thesis and the figure itself limit the visual information.

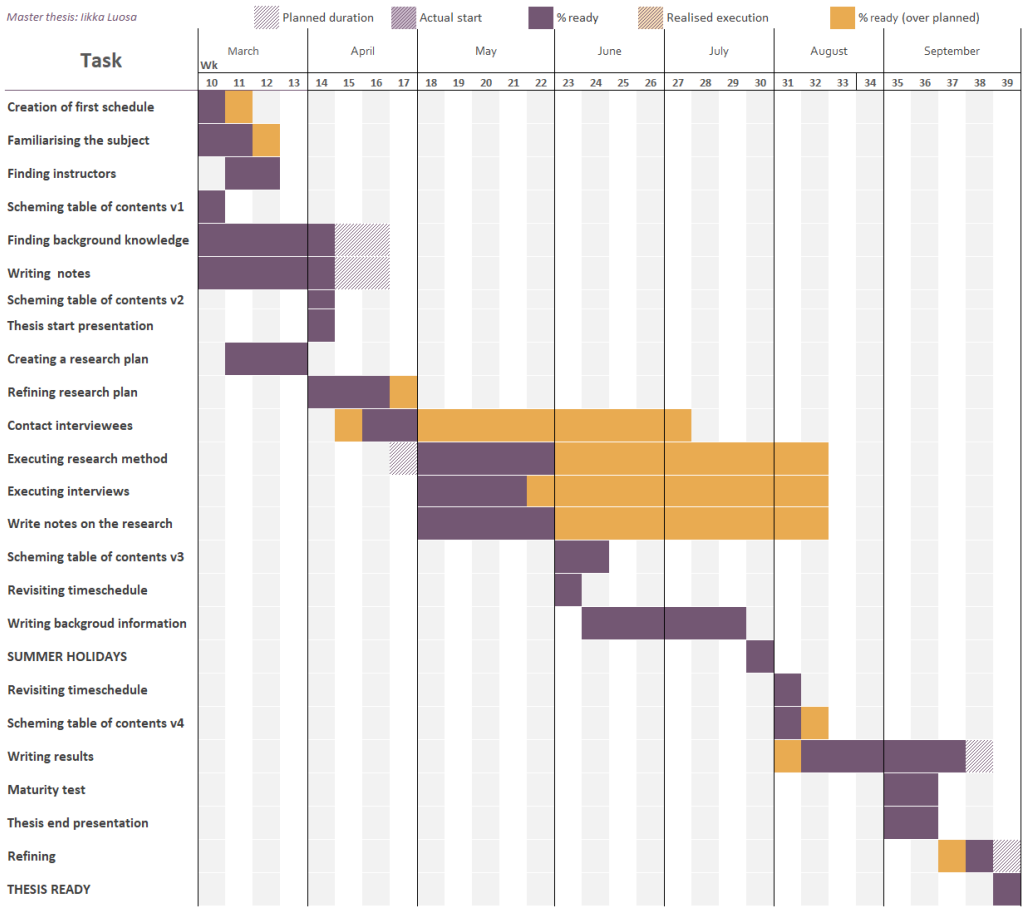

Figure 2. *Gantt -figure of the thesis process*

The supervisor from the case company took initiative to the definition of research as well as to the whole process of the thesis work with the researcher. Especially in the beginning all the support was needed to guide the research towards rewarding results. The research is discussed in more detail later in chapter 3. The middle phase of thesis work was full of independent work, but towards the end, the support of both supervisors, from the company and from the university, provided fruitful input to the work.

1.4 Study structure

This study is structured similarly to the standard structure of a research as suggested by Robson in Real World Research: A Resource for Social Scientists and Practitioner-researchers (2002). Naturally there have been left some room for uniqueness in the standard model to applied here. The first part of structure strives to flow through with basic introduction to the study itself, specific background information and the definition

of used research methods as it is the commonly accepted method, as seen in figure 3. In the end the results are generated as a case review and a discussion chapter summarises the whole opus as well as providing future insights.

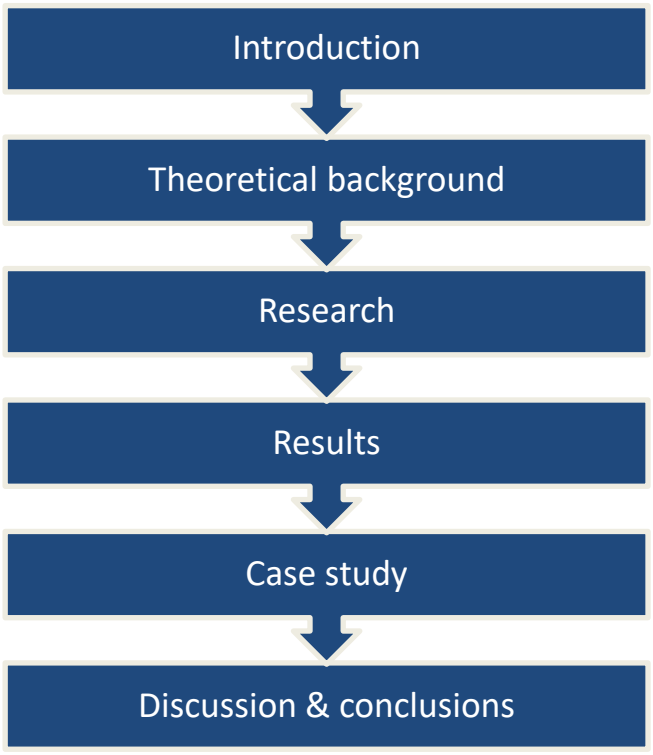

Figure 3. *Study structure presented visually*

The introduction aims to provide a basic overview of the premises for the thesis. An introduction of the case company was added to the standard structure. The company overview provides information of the general business model and range of operation. Focus is guided towards the products to give the reader better understanding and some perspective over the rest of the thesis, as the structure and the research was planned to benefit the development of the case company. Next chapter pursuits to address the essential background information in order to support the research findings and the conclusions driven from it. The key concepts revolve around defining the service in this specific context, manging life cycles and understanding the company portfolio.

The research method chapter is opened with the definition of used method and continues to discuss the execution in a more detailed way. The research provides the

results and in the case study the research results are combined with the background information to create knowledge. Based on this knowledge a model proposal of service life cycle for the case company is created and presented. The thesis is concluded with a discussion over itself to provide notions of lessons learned and points of improvement.

The thesis writing process has been conducted while keeping in mind the reader, in general, the thesis pursuits for ease of reading. Simplicity has been the key word to keep the flow and structure of the thesis clear, while the actual process has taken complex form at times. In order to support the reader comprehension and discussion in the text, figures and tables have been added throughout the opus. In the end, hopefully the reader has gone through a clear path and can find a well-founded progress through the thesis.

1.5 Overview of the case company

Serres Oy is a Finnish family company providing liquid management solutions to hospital operating theatre. In 1985 established Kauhajoki based plastic production company has developed from a local handyman company into an international niche company competing with quality. Serres headquarters are still officially based in Kauhajoki, Finland, even though the company is leading Europe markets and providing top competition in Asian markets. The pursuit to USA markets, the globally greatest health care markets, is on their way, as Serres Inc. has been established.

During decade 2010 Serres has steadily employed continuously just under 200 people, most of them in their production site in Kauhajoki. The turnover during said year was a steady 28,8 million euros, as it has been between 25 and 28 million for the 2010-decade. The company net profit has been positive for this period, which is reflecting the consistent development and long-term commitment characteristic to a family-owned company. (Wacklin 2013)

Nowadays Serres Oy itself is a part of a larger management group called Serres Group Oy that is still managed by the founding family Jyllilä. Today the Serres Group consists of Serres Oy, Vieser Oy, Innokas medical Oy and the latest addition Cubist. Vieser Oy is similarly a plastic productization brand, but namely for liquid draining in housing for example floor drains. Innokas medical on the other hand was the target of major acquisition for technical and assembly reasons regarding technical devices. Cubist has been added in the late 2010's to reinforce the necessary information technology know-how to overcome future challenges.

Serres business revolves around liquid management. The operating theatre has strict and specific quality needs. The operating doctor visuals provided by suction equipment is at an utmost importance in general open-cut surgeries but regarded as a necessary safety measure in every surgery. On the other hand, the suctioned liquid is considered as biologically hazardous waste for the infectious disease potentiality. Thus, Serres is providing suction bags and related equipment to provide basic suction and is currently generating appliance to provide automated suction and safe suction liquid waste management. The current basic products are pictured in figure 4. The main services revolve around value analysis provided for the customer as well as basic customer service including product implementation and training of staff.

Figure 4. *Serres suction bag system and automated evacuation device (Serres, 2019)*

Serres is heading into global markets with their devices while relying on to generate more value with the actual devices and related services. The challenges range from market share acquisition to founding and maintaining service organisation as well as continuing with steady consumables sales. Continuing with a family-centred ownership and expanding the quality associated brand simultaneously is an enormous feat to overcome.

2. THEORETICAL BACKGROUND

In this chapter the theoretical background for this thesis is discussed. The selected theories can be divided roughly into three different areas. The first segment covers theories for services in this context from different types of services to productization and culture. The last part discusses life cycles of products, customers and services. The middle segment aims to cover the ideas of product portfolio turned into productized service portfolio. This chapter aims to provide solid foundation to build the research results in a way to provide a vision of service life cycle model.

2.1 Definition of service

Service is a widely used term with multiple functions in language. The variety of applications in communication spans from maintenance related actions and purely conceptual value creation to expressions of spoken language as serving one's country. In this thesis the definition of service is in the scope of company-customer -relationship and moreover as the physical and non-physical actions from sales and customer service to actual device maintenance.

The Oxford dictionary of English defines service as "the action of helping or doing work for someone, an act of assistance, a periodic routine inspection and maintenance of a vehicle or other machine" among other things. When diving deeper into the maintenance aspect of service, said definition clearly states an action of person for another person or a device. The action is performed because the serviced party lacks the skills, resources or accreditation to perform this act themselves. By nature, this is considered as value creation for the serviced party. Still the types of service, and thus also type of value, varies depending on the company-customer -relationship and the customer need. Inside the medical device field, the needs of customers are quite static and regulated by authorities both in financial and safety fields. Nevertheless, the medical field has its own special aspects when it comes to service culture and this is discussed more in the appropriate chapter.

2.1.1 Service categorization

Services as a maintenance operation can be categorized in multiple ways. In this case we are using categories of **reactive, preventive, predictive and proactive services**

(Dorne *et al.* 2008, p. 139-152; Bell 2008). This division is widely used as it covers the whole field of services while concentrating to keep the product itself in the condition of function.

Reactive services are generally considered as the easy way out, as the service provider reacts to the need of customers. The customers reach out to the provider as their product has countered a defect. This leads to a proper reaction within the service provider to counter the defect. A real-life example of reactive service is a situation where a car breaks down during use and a service team must react to the owner's needs by coming to fix it.

Preventive services on the other hand require foresight and product familiarity from the service provider. This type of service is provided before the actual defect in order to prevent the state of failure. In other words, machines in complete functional state are serviced to counter possible breakdowns in future. The scheduled service plan might be based on used or performed units for example mileage or based on simply the time between services. A real-life example of this case is a manufacturer required regular maintenance of a car.

Condition based service differs when compared to time-based service or maintenance. Basic concepts of condition-based services are predictive and proactive services. These two rely on the actual condition of the product instead of averaging calculated time between maintenance. Predictive service is provided as conditions that do not prevent the safe use of the device are noticed. This condition is mended during routine maintenance before breaking down in order to continue the proper functioning of the equipment. An example of predictive service might be a note of wear-down in a disposable part from mechanic to the car owner during a regular service. In this special case the decision to really execute predictive service might be up to the owner of the car.

Proactive service on the other hand is driven from within the company. Proactive services include pre-planned strategies on how to respond to or avoid possible customer service issues. These strategies vary from customer service contacts; calls or letters, to actual maintenance in the case of a defect in product development phase. An example of proactive service would be a car manufacturer calling back certain sold cars for a free maintenance in order to avoid catastrophic collapse of performance. These service types are briefly summarized in table 1.

Table 1. ***Summation of basic service categorization***

Service type	Definition	Example
Reactive	Service organisation reacting to customer need after a state of failure in a product.	A broken-down car during driving. Adequate help is sent.
Preventive	Service organisation reacting to former experience of failures in products before customer experiences a state of failure.	Mileage based services in cars.
Predictive	Service organisation reacting to actual state of a product before customer experiences a state of failure.	A wear down is inspected during a regular check-up and this part is changed before it causes a state of failure.
Proactive	Service organisation discovers a possible cause of failure in their product and takes according steps to prevent the user experience of failure in the product.	A product call-back for maintenance because of inspected cause of failure in car manufacturers production process.

As seen above the service types are distinctively different and are required in different phases of organisational and product development. The predictive and proactive strategies are usually implemented more in a new product as those are prone to generate completely new failure cases. Compared to former, reactive and preventive strategies are implemented in cases when the wear down and failure cases are generally known and quite stabile. Thus, the time-based principle can be applied, and the organisational load is lightened as the cases grow more familiar and familiar. Combined all these strategies provide a spectrum of adequate services when utilized according to the product, its intended use and lifetime.

2.1.2 Productized service

Productizing services is an act and a result of forming clear **product and service bundles** to a whole in order to attend the needs and expectations of customers. There can be seen two levels in productizing: what is visible to the customers and what is visible inside the company. The customer experience regarding to productizing is condensed to the marketing material in form of pricing and service inclusion. Inside the company

productizing has more broad effects as the processes, roles and responsibilities must align with the efficient customer experience. In its essence, productizing aims to find a balance between standardizing and customization. (Martinsuo *et al.* 2018, p. 10-22)

The decision to start a productizing process should start by identifying a possible service to productize and continue carefully comparing the opportunities and threats it holds. Potential services for productizing are characterized by the following aspects.

- The productization of this service aligns with the company strategy
- The service is economic to produce or has economical potential
- There is experience inside the company to run the service
- There exists a repetitive customer need for the service
- There exist repetitive tasks in the service process

(Tuominen *et al.* 2015, p. 8)

First and foremost, as any business-driven company, the end goal for the whole organisation is to generate profits for the shareholders of the company. Secondly, in the ideal situation, the need for productizing a service springs from within the company. The existing organization discovers a repetitive pattern in their process and the productizing can be built on their experience. Finally, if the productization is in alignment with the company strategy, there exists significant potential in the productization of considered service.

Generally, the reasons companies pursue to productize their services revolve around finance. The services become more uniform and **repeatable**; thus, the process doesn't have to rely on single individuals. Furthermore, when services are uniform and repeatable, also the marketing and sales is simplified as the communication through the service process is also in uniform. A successful uniform service creates dependency. A functioning service might just provide the key value in customer's value chain to make it irreplaceable. On the other hand, one should be aware of the threats in productization. When balancing between standardization and customization the customer experience is too easy to forget. This leads to fixed model of service, which is not the point of productization, but a possible outcome. On the organizational level, if the process is

pushed through without the inclusion of the staff, this negative spiral might continue down to lack of motivation and even resistance to the change. The path to success is narrow.

It is also noteworthy, that productization leaves room to provide different levels of service. Separation to basic, advanced and value-added services is a business strategy, in which by paying more the customer gains more (Sakao *et al.* 2009, p. 93-111). The higher of service level the customer engages in, the higher priority they will gain, the faster service and the more customized output they are entitled to.

In today's environment, even entrepreneurs are able to productize their services as internet and information technology are enabling skilled persons with the necessary tools. Let's use accounting as an example. Traditionally accountants charge for their time as a basic service. An experienced accountant is able to create service packages like 'yearly accounts' or 'taxation' to engage clients into, instead of the traditional mode of pay per hour. This leaves room for the accountant to optimize their time spent on a client while still charging the amount markets have saturated to. Even further the premium class clients might receive information directly to their own information processing program in their desired deadlines and so forth. This shows that, when used properly, productization provides competitive advantage in business.

2.1.3 Culture and medical field

Culture is the behaviour and actions of people as well as the communication between individuals and groups. According to Schein (2010, p. 23-35) culture has three levels: artefacts, espoused beliefs and values, and basic underlying assumptions. Artefacts are the visible aspects of the culture like processes and ways of communication. Espoused beliefs and values on the other hand are the ideologies and rationalizations held by a group. These aspects of culture one cannot see, but these still might be acknowledged by the members on a conscious level. The foundation level, basic underlying aspects, are the unconscious beliefs and values, that are taken as given, since there is no conscious rationalization when absorbing these aspects from the culture. These levels are visualized in figure 5 for ease of understanding.

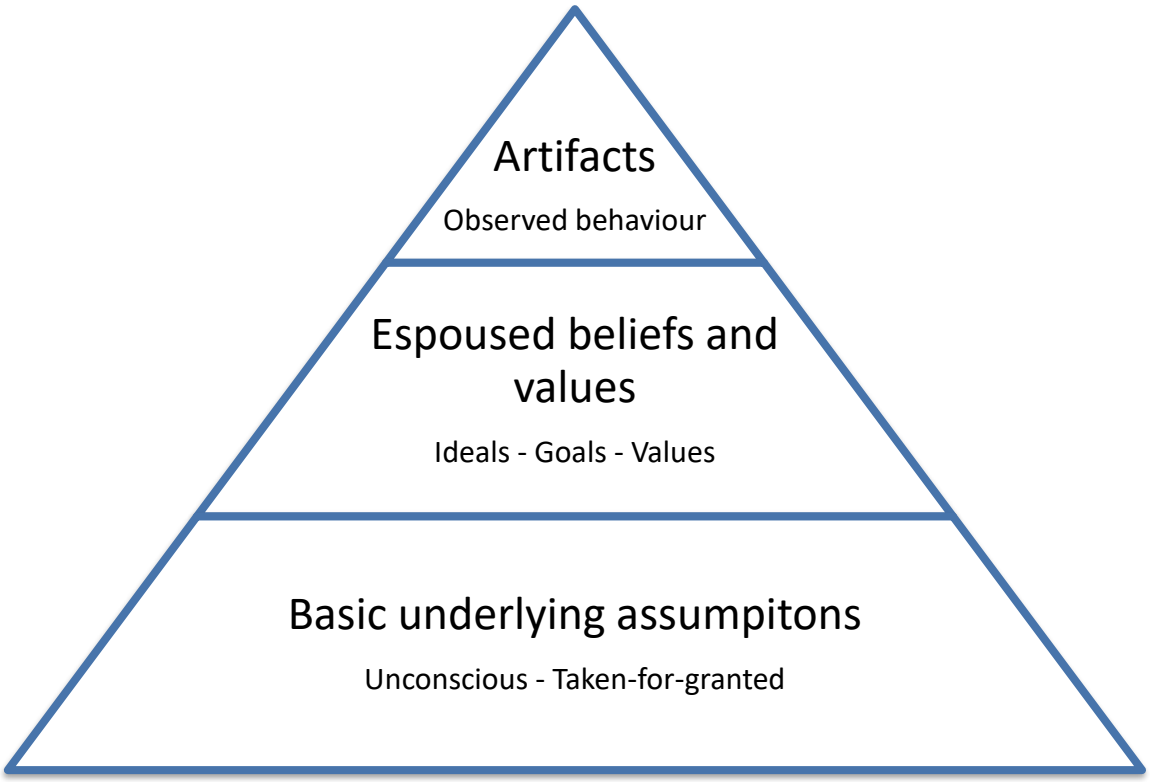

Figure 5. *The three levels of culture (Adapted from Schein 2010, p. 22-35)*

These levels are visible in virtually all cultures around the world, but there seems to be six main dimensions in both local and organisation cultures that determine the actual culture. These dimensions have been identified in order to provide benchmarks on which to compare cultures. The nature of behaviour is difficult to measure or even to describe, but some common dimensions seem to be found common in different publications (see for example Dimmock *et al.* 2002, Hofstede 1994, *Walker et al.* 1999). Inside local cultures these axes, if you may call them, are adaptations from the mentioned publications. The dimensions themselves are quite intuitively explainable, but to be sure, they are further explained in tables 2 and 3.

Table 2. ***Local culture dimension descriptions (Adapted from Dimmock et al. 2005, p. 29-31)***

Local culture dimension	Description
Power-distribution *vs*. power-concentration	Is the power in the society in the hands of few or in the hands of many, i.e. distance of power? In power centred society the power is in the hands of few and generally the inequity is common, and *vice versa*.
Limited relationship *vs*. holistic relationship	In cultures with limited relationships the communication is fixed around certain rules of conduct in certain situations. In holistic cultures on the other hand, the personal considerations drive the focus in communication and more emphasis is given to kinship- and patronage -like aspects.
Group-orientation *vs*. self-orientation	How do individuals see themselves in the society? If they see themselves first as individuals, and second as members of the society, they live in a self-oriented society. In the 2010's this can be sensed as generally Asian cultures are considered highly group-oriented compared to the other end of spectrum self-oriented Scandinavian cultures.
Consideration *vs*. aggression	In aggressive cultures achievements are highlighted as in cultures of consideration the emphasis is on relationships and solidarity. Traditionally in culture this dimension is referred also as masculinity-femininity -axes.
Generative *vs*. replicative	There seems to be an indication towards some cultures being more predisposed towards generating new ideas, or innovation, as some cultures are lenient towards adopting ideas from other cultures (to replicate).
Proactivism *vs*. fatalism	Proactivism, more like "we can change things around here" -attitude is compared to the fatalistic, or "what is meant to be, will be" -attitude. This description has relations to traditional dimensions such as uncertainty avoidance -axis or locus of control.

As seen from table 2, the dimensions shift from individual feeling, such as group-oriented *vs*. self-oriented dimension, to more general population descriptive, such as the distance of power. These aspects provide depth into understanding of other cultures. These aspects become visible for everyone after absorbing the theory information for example during travelling. It is clear how the physical distance between cultures has been able to generate such a division in population behaviour. Thus, the balancing in local culture between individuals and their efforts compared to a nationwide, or even

continentwide perspectives is an ongoing feat. When transitioning to organizational culture the wide end of the spectrum is decreased to thousands of people.

Organizational cultures naturally mimic the local cultures as they can be seen as subcultures. Subcultures are embodied inside a local culture another tightly knit community generates their own culture, for example organisations in companies are great examples of how there are different methods of communication and way of performing. In this thesis organisational cultures are an area of interest, and that's why they are explained in more detail. Their dimensions have evolved from local cultures to more suit the needs of profit pursuing actions of a company. These dimensions of organisational cultures are adapted by Dimmock *et al.* (2005, p. 63-78) to follow the ones introduced in table 3.

Table 3. ***Organization culture dimension description (Adapted from Dimmock et al. 2005, p. 32-35)***

Organizational culture dimension	Description
Professional *vs*. parochial oriented	How do the members identify themselves? Are they more inclined to identify themselves with their professional standards or with their particular organization?
Pragmatic *vs*. normative oriented	This dimension strives to explain the way an organisation serves its clients. Is it aiming to provide a pragmatic or flexible policy meeting the customer needs compared to a normative i.e. bureaucratic services that are expected to be needed for example tax offices?
Process *vs*. outcome oriented	Process stressing organisations lay emphasis on the way of performing or processing itself for example process oriented schools stress the learning process and decision making. Outcome oriented organisations on the other hand highlight the outputs, whether it be profits or GPA, and the methodology behind this achievement is a smaller priority.
Task *vs*. person oriented	Task-person-orientation is in its extreme a balance between maximizing productivity and staff welfare. Person-oriented organizations promote welfare for its employees compared to task-oriented cultures strive to maximize to effort or value gained from its employees.
Control *vs*. linkage	This dimension pictures in more detail how the control and authority are communicated between organization members. There can be seen 3 additional subdimensions inside control *vs*. linkage; formal-informal, which explains the lenience towards bureaucracy; tight-loose, which explains the degree the members feel the ideals and values are shared through the organisation; and direct-indirect, which explains the patterns of communication between different hierarchy levels.
Open *vs*. closed	Open organizations are said to easily exchange its resources (money, workforce) with its environment, and vice versa in close organizations.

As further seen from the tables 2 and 3, the dimensions in both local and organizational cultures have similarities as seen in limited relationship *vs*. holistic relationship -dimension description. Additionally, they have distinctive differences as

seen in different setting of authority for example power distance compared to linkage of control and furthermore in the direct-indirect dimension. This provides the need for the separation in definition. In medical field these dimensions are visible too, but more in specific details. These details might not be unique to medical field, since some stem from organisational culture and some from local cultures.

In medical field, and especially in hospitals, patient safety is an extremely important, but new concept as Waterson (2014, p. 1-43) explains. Working in an environment which hold personnel from multiple educational and cultural backgrounds as well as is filled with fast phased, life critical choices and actions is providing the chance for errors and malpractice. The **regulations and requirements for medical field** are specific in terms of errors, hygiene and certifications. (Imhof *et al.* 2013, p. 1-15; Waterson 2014, p. 43-99) Moreover, when diving deeper to medical field the different roles and facilities hold different risks and cultural peculiarities. Safety culture is generated from awareness of these roles and risks. The risks include safety aspects such as devices, the operating personnel experience, and the safety culture itself. If the culture is violated and neglected it might nourish the risk factors for example in hygienic actions.

Hospitals too are influenced by the prevailing local culture. There are aspects of self- *vs* group centred actions as well as proactivism *vs*. fatalism ideology in personnel. Additionally, as the organisational culture is subject to the organisational culture visibly in the term of task *vs* personnel dimension. In most nations this is visible to the public through differentiation to state-run and private-run hospitals. The central difference here is the profit driven decisions in private-run hospitals compared to state-run hospitals. It is a common feature in state-run organizations to lack pressure of performance or demand for profit. This is usually experienced as slower pace of action but also as consistent care results.

In relation to discussing culture and medical field, this chapter only scratched the surface. All hospitals are subject to unique culture of action. Culture of action here holds example steps like preparation for operation and more extensive roles of service personnel to device utilization. To understand the effects and requirements of a single hospital as a customer one needs experience of cultural differences and acknowledgement of the reasons behind these aspects. The scope of publications and research on culture is vast and even the medical field has multiple points of view left undiscussed here. For the sake of limiting the thesis the aim is to demonstrate only the basic dimensions of culture and the connection between medical field safety and culture.

2.2 Product management

A product is defined by Merriam-Webster dictionary as “something (such as a service) that is marketed and sold as a commodity”. These commodities are exchanged to an amount of currency between the provider and the customer, and that’s how the world works. Inside companies there are organisations, where people with different roles strive to provide the customer an optimal product for all sides. Profit driven organizations are created around a product or a service and sometimes multiple products. The same principles of company management can be applied on product management since a product can be thought as **a small business inside a larger business** with own finance and resource management. In the same way the objective in product management can be put briefly as to increase the profits on a specific product both on short term and long term (Handscombe 1989, p. 1). Naturally the actual responsibilities of a product manager vary between organizations, but the baseline is similar. The product manager is in charge of, or in control of, the sales, the research and development (R&D), and the manufacturing process around said product. How these different roles of a product manager are emphasized depends greatly on the phase of the product life cycle (Lehmann *et al.* 1994, p. 12-13).

There are two distinctively important functions in the role of product manager. First objective for the product manager is to oversee the planning of different actions during product life cycle, be it the R&D in the early phase or the market entry strategy later. Secondly the product manager should support the product organization when acting on the managers decisions. This complicates the role of the manager, as they must interact with different levels and departments inside the company from the assembly line all the way to the executives. (Lehmann *et al.* 1994, p. 1-2)

Inside the case company there are two different product groups that are managed separately. Both groups are responsible for the product management and product development for all the products inside the group. The division is based on the function of the products but for the moment there is an evident difference between both groups in their products life cycle phase: One is just ready for launch and the other has already gained a share of the market. The organisations in both groups have been quite stabile, but as the life cycle progresses it is only natural for the organisation to develop around it too.

2.2.1 Company portfolio

Company's portfolio is the totality formed from concepts of service and products inside the company, that can be offered to be configurated for customers (Martinsuo *et al.* 2018, p. 5). This totality might consist of different categories and are in line with the company's strategy. On the other hand, Chatzipanos *et al.* (2018, p. 5-15) define a portfolio as "a logical group of components managed together to achieve certain strategic objectives." The components include manageable entities such as subsidiary components, projects and programs and they can be related or unrelated to each other. Related in a way that they are offered to the same customer or unrelated as of localized in different cultural areas. In the scope of this thesis, the portfolio comprises of the definition first mentioned as the thesis focuses on the provider – customer -relationship and aspects revolving around it.

The portfolio consists on the higher level from services and products. This is an intuitive, but also organisationally reasonable division, as generally different people are responsible for these segments. Products can be the company defining aspect for customers as in case of Nokia. Nokia phones can be seen as a company defining product group holding alongside its different network solution products. Unfortunately, Nokia phones gained an unsustainable momentum or focus from the company, leading to its demise. (MarketLine 2012, p.2) The other usual segment is services. Services include multiple product and operation specific modules. These modules can be described in an extremely detailed manner in order to maintain steady level of performance inside a company. (Martinsuo *et al.* 2018, p. 25-44) In the figure 6 the portfolio is kept on a general level to keep it more versatile for different applications.

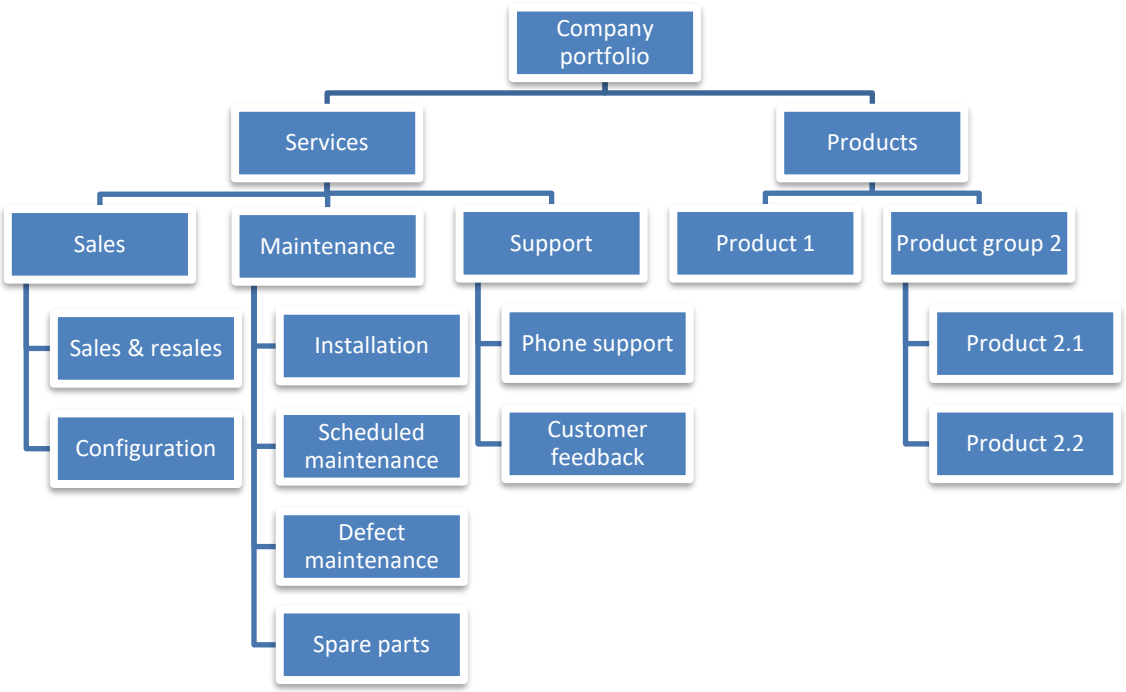

Figure 6. *Simple company portfolio (Adapted from Martinsuo et al. 2018, p. 10-74)*

The segments and their modules in any given portfolio are blended in order to truly create a configurated offering for a customer with specific product embraced with the right service plan. Transforming requirements are met with a comprehensive and detailed company portfolio.

Maintaining an extensive portfolio is demanding and the portfolio management is a highly strategic role to further the company's agenda. While striving to make strategic decisions over market information on products and technologies, portfolio management also includes the action of **allocating resources** on suitable portfolio objects and decisions of focus (Cooper *et al*. 1999b). In this study Cooper *et al.* also published an academic definition for portfolio management:

> *"Portfolio management is a dynamic decision process, whereby a business's list of active new product (and R&D) projects is constantly updated and revised. In this process, new projects are evaluated, selected, and prioritized; existing projects may be accelerated, killed, or deprioritized; and resources are allocated and reallocated to the active projects. The portfolio decision process is characterized by uncertain and changing information, dynamic opportunities, multiple goals and strategic considerations, interdependence among projects, and multiple decision-makers and locations."*
>
> *Cooper et al. 1999b, p. 335*

This brings more light on the fact how complex the portfolio management really is. Furthermore, appropriate portfolio management supports efficient resource utilization, reinforces the company strategy and intensifies maximization of portfolio profits in the long run. (Oliveira *et al.* 2010, p. 1339)

2.2.2 Product-service systems

Product-service systems (PSS) can be defined as a marketable set of products and services capable of jointly fulfilling user's needs (Sakao *et al.* 2009, p. 31-49). PSS is a widely researched area and there are small deviations in the definition, but the stated definition is proper in the context of this thesis. The main reason companies are adopting the PSS method is profits. The system relies on the idea, that customers are more inclined to buy the results achieved with the products and services, not the actual products and services themselves (Manzini *et al.* 2003). This way the providers can move to providing **value of utility instead of ownerships of a product**. Furthermore, this means to provide the results of the product-service system when the customers want it without customers having to mind the maintenance or disposal of the product.

Basically, this could be pictured as a development of a company selling laundry washing machines. In the start this company is selling the product with a fixed price for customers. As they notice a considerable pool of their customers to be companies, which are generally only interested of providing clean clothes to their employees, not of owning and maintaining a washing machine with their own results, the laundry machine company sees a chance for development. Providing companies with a PSS of washing service, they are able to expand their customer field as well as increase profits. New pricing could be based on times of laundry wash or perhaps a monthly subscription and this is pictured in figure 7. (Sakao *et al.* 2009, p. 31-49)

Figure 7. *Simplified PSS pricing (Adapted from Sakao et al. 2009, p. 34; Pngimg)*

By the nature after changing to the model of PSS pricing the company must be more aware of the state of their products state. Today this kind of monitoring is already provided through internet in various businesses. The monitoring provides valuable information on the product through its life cycle, which can be utilized to forecast future incidents for other similar devices.

Additionally, there are two alternating arguments of the environmental effects of the PSS. On one side this system encourages providers to maintain and upgrade their products and later reusing them (Mont 2002). Unfortunately, still the waste management costs might be significantly lower than repair costs. On the other hand, PSS enables the customer to spend their saved resources in an unsustainable way (Manzini *et al.* 2003). Therefore, there is no consensus on the environmental effects of the PSS.

2.2.3 Medical device regulation

Medical devices are special as products. They are used in healthcare and are under locally varying severe regulation. Healthcare products and devices are governed tightly, since they are directly or indirectly in contact with patients and this way effecting patient health or diagnosing their condition.

The regulating authority is usually governed by a state or a country in which the authority operates. For example, in China the authority is called the China Food and Drug Administration (CFDA), but this will soon be reformed into a single market supervision administration with other administrative bodies by the state (Pacific Bridge

Medical 2018; Daniel 2018). In the United States of America, the authority is simply called the Food and Drug Administration (FDA), and inside European Union (EU), the European Commission is responsible for the regulation of medical devices among other things. Although in EU the independent countries in many cases have their own governing officials to see the EU directives fulfilled, such as Valvira in Finland. Then again, most smaller countries have their own officials, that mostly follows the regulation models of the greater business opportunity close to them. Still, there exists countries like Chile without any governing authority over medical devices so the variability on this planet earth is huge.

The regulation is performed through different processes and forms. When pursuing license to USA markets through FDA, one usually goes through a premarket notification, also called 510(k), on which the FDA can determine if the device is equivalent to a device already in market and placed in the same category of safety classification. This is called a predicate device. Otherwise with a completely new device or a method, the company is responsible to assure FDA of the safety of the device with comprehensive testing and documentation. (FDA 2018) Inside EU the regulation process doesn't usually involve a predicate device but multiple forms of conformity with different standards and directives as well as an approval from a notified body. These notified bodies are authorities in different field licensed by European Commission to grant CE-marks. CE-mark is the license for a product to operate inside EU markets. (European Commission)

European Commission is harmonizing and specifying its regulation all the time. At the moment there is an ongoing transition time to the two newest medical device regulations that will replace three older medical device directives by the year 2022. These regulations consider for example the Unique Device Identification and strengthened post-market surveillance requirements for manufacturers, among other things. (Regulations on medical devices 2017) There are multiple standards and directives that are still applied on medical devices after this step of harmonization is done for example ISO 13485:2016 – (Medical devices. Quality management systems. Requirements for regulatory purposes) and ISO 14971:2007 – (Medical devices. Application of risk management to medical devices) and only future shows how this process progresses. It is noteworthy, that the regulation authorities only provide a license to operate on their markets, they do not carry any liabilities or responsibility of the device. The device is still solely the responsibility of the manufacturer. In the new Medical Device Regulation, the EU commission has strengthened the responsibilities of manufacturers. This is seen as the post-market surveillance is required now as an active function instead of a passive

function. Thus, the manufacturers functioning in EU area are required to actively collect information on the use of their devices and strive to correct, document and report to the EU commission any defects. To support these new actions EU has provided manufacturers with forms and templates such as “Field safety notice template”, “Periodic summary report” and “Manufacturer incident report”. Also, there is a new unique device identifier clause, that forces the manufacturer to provide a unique and traceable identifier for all the devices. This way making the process of development more transparent and to prevent fake devices or black-market sales. In addition, there is an EU medical device database created as well as the clinical evidence investigations are enforced in more strength among other things. (European Commission)

It is essential in service to provide customers the relevant local regulation documents to satisfy the authorities and to ensure patient safety. These are the primary focuses when regarding service and regulations together. In addition, service provides valuable effort in post-market surveillance and is an essential part of fulfilling authority regulations. It is noteworthy, that this thesis is aimed to be applicable inside Finland and Germany, thus EU regulations gained significant weight in the chapter.

2.3 Life cycle management

Life cycle management (LCM) is a concept and a process used in companies to guide their actions and products as an organisation. It is used to address the **environmental, resource and economic aspects through**, as the name gives out, **the whole life of a product** or service from manufacturing to repurposing. LCM also provides a tool to evaluate the supply chain *i.e*. downstream activities as well as the customer’s and their customers’ activities while maintaining a vision for all the more needed sustainability in value creation. (Sonnemann *et. al*. 2015, p. 3-6)

The idea of a life cycle is nothing new, it has existed already for a long period of time, especially in the fields where product lifetime is long such as power plants and cargo ships. Nowadays even shorter and shorter life span products are produced through LCM as the efficiency requirements to reach markets are growing. Generally, but especially in marketing, LCM can be seen to cover phases such as introduction, growth, maturity and decline. (Stark 2005, p. 17-21) From the most common ones, in table 4 are pictured the relevant life cycle paths for this thesis: general idea of life cycle, manufacturer viewpoint and customer point of view.

Table 4. ***Different views on life cycle management (Adapted from Stark 2005, p. 17-18)***

Time	→			
Marketing	Introduction	Growth	Maturity	Decline
Manufacturer	Imagine & Define	Realise	Support & Service	Retire
Customer	Imagine & Define	Realise	Use & Operate	Dispose & Recycle

These phases are applied in different ways as is shown in table 4. Different aspects are highlighted in different stages of the life cycle. Introduction phase covers the start of life phase, where a product or service is brought to life. It may be introduced to the markets, or in the manufacturer point of view, the product could be realized form raw resources to a marketable entity. It is vital to ensure that customer needs are met from the introduction phase onward. Next, the growth phase pursues to explain the challenges and actions to be taken in order to scale up the manufacturing or to increase the sales. Briefly put, in the early phases the developing and the marketing of the product are seen to be important. Emphasis is put on reaching the strategic customer segment or the essence of functionality, depending on the viewpoint. (Anderson 1984)

The third phase, maturity, usually defines how the technology, product or service has reached its life cycles peak point in terms of users, sales, or popularity. There are multiple studies conducted on life cycle phases and especially on the maturity phase of the life cycle (see for example Hamermesh *et al* 1978, Hall 1980). Briefly put the emerging results are quite logical for the main events in this phase; to scale up and to streamline the production; specifying the market segment; and cutting the costs in production, marketing and distribution as well as service. (Stark 2007, p. 115) This phase is the most visible in the eyes of customers and could be seen to withhold a life cycle of its own, a customer life cycle.

In the end, the decline phase pictures how the popularity of certain commodity is fading. The life cycle ends, as something else becomes more popular or offers something

more valuable for the customers to use. The differentiation in the last phase is focused on whether the exit strategy for the life cycle is extended or if the strategy is an immediate exit. (Saaksvuori *et al.* 2008, p. 207-220)

Life cycle management is a complex process with multiple stakeholders, thus, there are different ways of seeing the actions during LCM (Harrigan 1980). Even thou the economic performance varies, still the path to maximized product profits is often based on sustainable and steady revenue streams during the whole life cycle process (Steinhardt 2010, p. 97-111).

A noteworthy point in the aspect of devices and life cycle management, is life cycle cost (LCC). LCC is the result of life cycle cost analysis, in which all the costs or transactions during a product life cycle are analysed. Traditionally these costs include at least the price for ownership, cost of use, service plans and possible consumables but to supplement it, it is recommended to also provide the customer recycling services and possible calculations of saved resources compared to the competitors. LCC is an efficient comparative when comparing offerings from a customer point of view. (Klyatis *et al.* 2016, p. 70-71)

2.3.1 Service in customer life cycle

The typical customer life cycle follows the basic guidelines of life cycles: it has a beginning and an end. Moreover, customer life cycle starts with contacting through marketing and sales, continues with configurations and installation, provides value in customers process and moves towards repurposing through modernisation as the customer's requirements change. (Martinsuo *et. al* 2015, p. 58-73) Customer relationship management (CRM) is the method that consists of mentioned aspects as a company driven function. Basic customer lifecycle phases are visualised in figure 8.

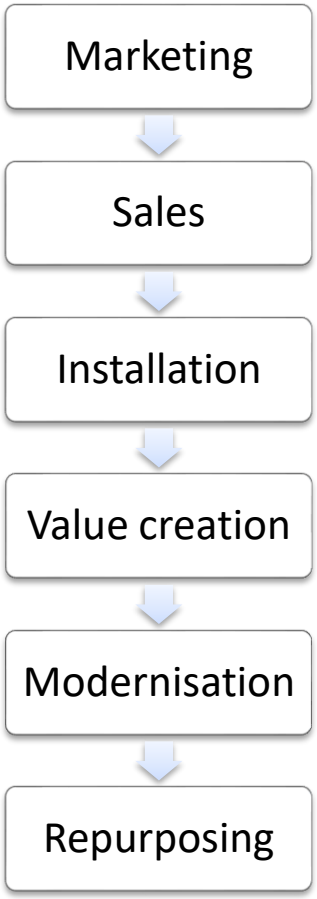

Figure 8. *Customer life cycle phases (Adapted from Paloheimo et al. 2004, p. 10-40)*

Marketing in its essence is to reach out and grab the attention of a possible customer. This is a complex process with multiple different strategies as 1 *et al.* (1999a) explain. After catching the interest of a possible customer, sales process is started. It usually combines creating an offer for the customer according to their needs. These specific needs might lead to configuration of the product or service offered. Configurations may include but are not limited to guidance by the customers facilities, resources, culture or visual preferences.

Installation is an important part of service during customer life cycle especially with medical devices. It is the where traditionally the ownership of the product or device is handed over to the customer. (Martinsuo et. al 2015, p. 6-19) Briefly put, in this phase the manufacturer or provider must secure the correct and safe functioning of the

commodity exchanged. Some measures taken are electrical and mechanical tests and possibly training of customer staff by the provider.

Value creation is the reason this product or service was sold in the first place. Through this phase the customer utilizes the product in their process to provide a specific function. In practice this phase consists of a warranty period and the time after warranty until the commodity doesn't provide the needed value. This phase should include services such as spare parts sales, defect and scheduled maintenance, phone support and additional sales. Moving to modernisation phase is driven by the evolving requirements by the customer *i.e*. the product or service doesn't answer to the specific need in sufficient terms. Modernisation challenges the provider to maintain the connection to the customer through the whole life cycle to be able to react fast and accurately to the situation (Martinsuo et. al 2015, p. 39-54). The services could include a new cycle of sales, configuration and installation. In theory the customer remains in the customer portfolio of the provider if they are able to provide an answer to evolved set of needs with their modernisation services.

In the case modernisation is not successful, the customer life cycle shifts to repurposing. In this phase the sold service or product has lost its initial value and a new solution needs to be found. The solution depends on the contract and ownership regarding the commodity. (Martinsuo et. al 2015, p. 6-19) Physical products require recycling by the owner, and this could be included as a service to be bought from the provider, depending on the product it could be reused in the provider process. On the other hand, in modern society the recycling process and social pressure for more environmentally friendly processes is on the rise and providing safe recycling services are needed.

This process of phases could be seen to create a real cycle of customer life, as has been presented by Grönroos (1998, p. 1-68). Although the terms had slightly different terms, the theory follows the same logic from customer acquisition through sales and value creation to abandonment. Figure 9 was created by combining the cyclical figure from Grönroos (1998) with the phases mentioned before by Paloheimo *et. al.* (2004, p 10-40).

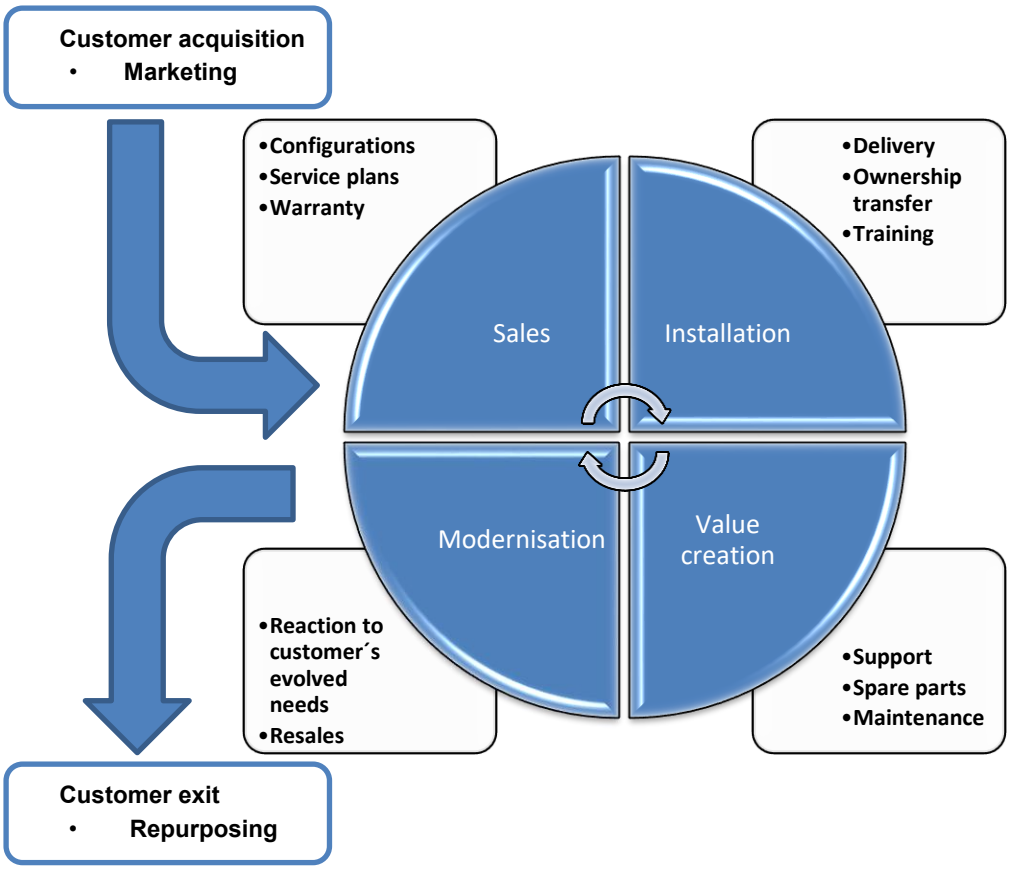

Figure 9. *Cyclical customer relationship life cycle with service examples*

In this figure we are able to present the customer life cycle as a piece of providers process where customer stays in the process from sales to resales through modernisation. In the figure there are examples mentioned of different services provided in each phase. The new customers enter via successful marketing and are adopted to the cycle, following an unsuccessful modernisation the customer decides to not continue the co-operation.

2.3.2 Modelling services

A model is an **abstract view on a system**. A model does not decipher the details in the system, as complementary models are developed to embody the interactions, behaviour and structure in more details (Sommerville 1982, p. 169-191). According to Martinsuo *et al.* (2018, p. 25-44) life cycle modelling is based on flows. These flows constitute from resources, information or work streams. Moreover, service process modelling is usually based on information for its immaterial nature. As service experience

is a unique event, precise processes cannot be modelled in order for the model to be applicable for a repeatable process.

Models have been embodied to visual constructions to ease the absorption of information. The information is presented in shapes, colours, text and pictures. The key information to include in a model regarding service and life cycle include parts as client inclusion, provider responsibilities, interfaces of information and individuals, life cycle phases and the services in question (Martinsuo *et al.* 2018, p. 10-48). Naturally the format for the model is an essential point when regarding the information content. Although there are various models such as a Gantt-figure and a task-diagram, an extensive example format of service models is called a service blueprint. Blueprint model is a form of process chart that focuses on the roles of different stakeholders during the action. They strive to picture the different interfaces and actions for each member of the life cycle as the desired service progresses. An example of a blueprint model is given in figure 10.

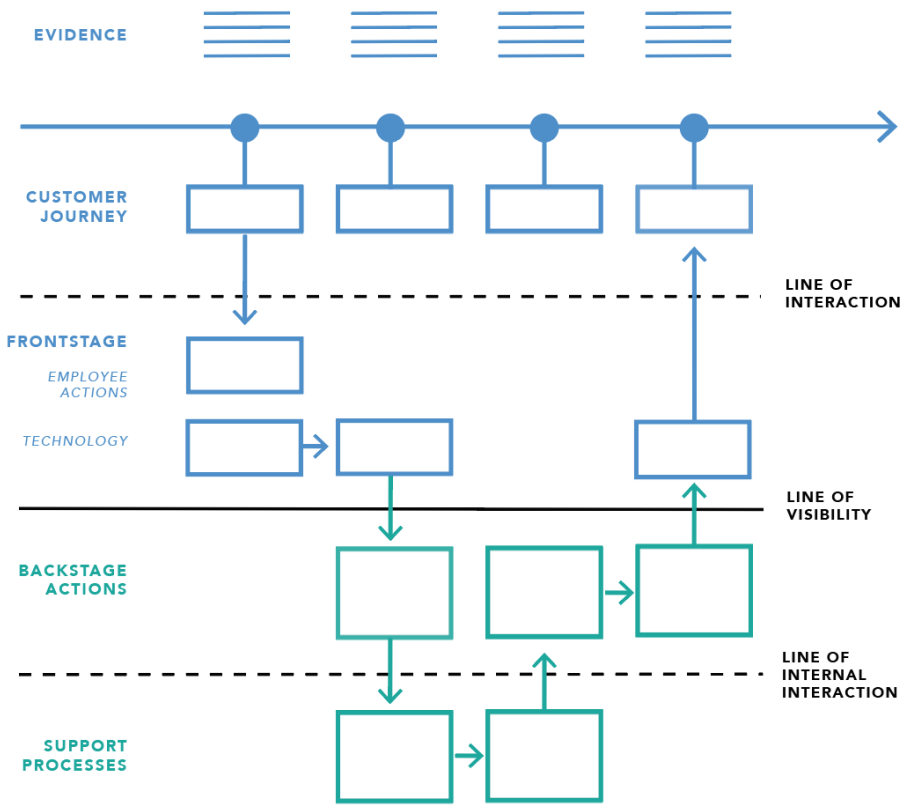

Figure 10. *Service blueprint elements (Gibbons 2017)*

In service blueprint, figure 10, time progresses from left to right. On the left side are the different stakeholders in this process. Line of interaction is to indicate, that the modules above it are in direct interface with the customer *i.e.* customer journey withholds the actions customers take during the process and the evidence are the physical manifestations for the customer. Line of visibility on the other hand pictures the threshold of what is visible to the customer for example phone support services and maintenance with technicians and salespeople. When moving beyond the line of visibility there are the backstage actions related to such roles as maintenance engineering, product development and product management. These functions are kept out of the customers view on purpose. The supporting processes are usually considered to include actions from different departments inside the company, thus crossing the line of internal interaction. An example of a supporting action could be spare part management. (Gibbons 2017)

Every model for a system should be a unique piece created for certain purpose. Thus, all models are representations of the information holders' views and it is their responsibility to convey the information. The main objective of a model is to communicate information to the viewer.

3. CASE STUDY METHOD

During this section the research in this thesis is explained in more details. The process is introduced to the reader and it is opened for discussion. After reading this chapter, the goal is for the reader to understand the reasoning behind researcher's choices and to gain the ability to critically evaluate the credibility of the study.

3.1 Goal of the research

Together with the case company instructing team, the thesis themes and goals were thoroughly discussed. The research goals were set as concrete as possible at the time. The discussions steered the main goal for the research to define the **essential service elements** for medical device producer, especially for the case company Serres Oy. These services are vital in order to provide a sustainable support for the customer during the use of company products. In order to define the must-have services, one should study the basic services in hospital environment. In addition, the assimilation of different service life cycle needs of hospital organization and the end-users is playing a significant role. Supplementing the previous aspects is the sub goal of understanding specialities related to operating theatre suction and services. The hierarchy tree of research goals is presented in figure 11.

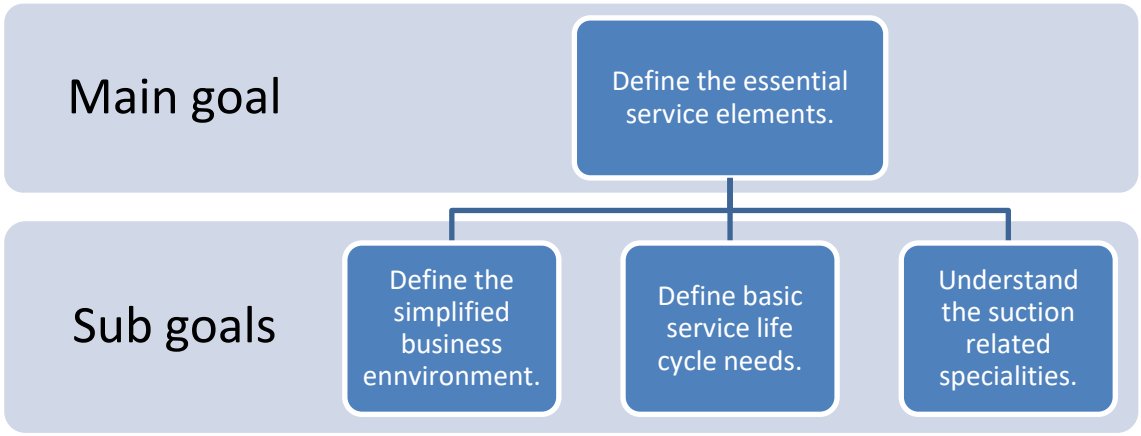

Figure 11. *Hierarchy tree of research goals*

As seen in figure 11, the research has a main goal, which is divided into three sub goals. This division is created for easing the research plan creation as well as later for interview structure composing. The interviews strive to provide a solid real-life experience to be built on the theoretical background that is searched for deeper understanding of the theory behind the practice. The research wasn't limited only for the use of thesis or company agenda furthering, the process was also considered as an opportunity to truly gain skills and specialty inside medical field for the researcher.

3.2 Semi-structured interviews

The type of information pursued in research is in key role when choosing the method for obtaining it. The researcher shall consider also the resources for how much of the data shall be collected, how will the data be analysed and what will be included. Furthermore, the quantitative – qualitative division of data is the foundation in method formation (Denscombe 2012, p. 91-108). The information strived in this thesis is clearly qualitative in nature: it is not measurable in numbers (Harland 2011, p. 26-31). Qualitative information can be collected in various ways. The most common methods are interviews through telephone or face-to-face. Between these two the face-to-face method provides more flexible question content, higher response rates, is appropriate for complex questions and permit visual aid for information conveying. Telephone method on the other hand is cheaper, easier to administrate, and has shorter time frame for data collection (Gubrium *et.al.* 2012, p.78). The decision was done for the benefit of face-to-face interviews, as per the wishes of the guiding group inside the case company. The company had profitable experiences in face-to face interviews and saw the method most fitting for this research.

The interviewees will be from different backgrounds personally and professionally. Thus, the information gathered from them comes through variety of communication methods: discussion, facial expression, e-mail-preference, voice tone, visual aids etc. This variety shall be considered, and the research method must not limit the gained information. In a case study the researcher should collect the data from all the means of communication the interviewees use (Pickard 2007, p. 97-110).

The method was further condensed to semi-structured interviews. The method combines the aspired personal contact with information holder, it doesn't itself limit the ability to gain valuable information, and it follows the academic research requirements. Semi-structured interview is a flexible research method. It progresses according to predetermined themes decided beforehand while leaving room for the discussion to take

a more natural path (Koskinen *et al.* 2005, p. 108). This fits perfectly to the idea of gaining more valuable information from face-to-face contact, while hopefully having a more personal relationship between the interviewer and the interviewee. This social constructivism is a philosophy embedded into the heart of semi-structured interviews. Basically, it allows the interviewees to affect the results of said interviews more, as they are seen to hold the valued knowledge consciously or unconsciously (Koskinen *et al.* 2005, p. 34).

There have been multiple articles written and even extensive studies conducted over medical devices, hospitals and service (see for example Brennan 2017; Calkin 2014). Still action research wasn't strongly represented in these publications even though the topics were in the same ballpark as this one. References for research execution were found on the field of industrial management and especially in social sciences where this type of research is more prominent (Lawson *et al.* 2015, p. 1-35).

For the full view on the service experience and culture, the research will include interviews from both inside Serres organization and the customer organizations as well as from Finland and abroad. The interviewees consist of Serres Oy service specialists, hospital biomedical engineering specialists and Serres Oy contracted service provider biomedical engineering specialists. The composition of interviewee pool is presented in table 5. All the interviewees were selected in pursuit of including people along the service chain from provider to customer roles. Additionally, the interviewees were selected in a way that all the levels had representatives from managerial and hands-on roles. The interviewees include also non-methodological information gaining communication, per the method should not exclude the information gained. In addition, this inclusion is supported by saturation theory, which is explained in more detail in chapter 3.3.

Table 5. ***Interviewee pool***

Date of interview	Title	Organization	Interview framework notes
3.5.2019	Product specialist	Serres Oy	Standard
16.5.2019	Device maintenance engineer	EPSHP	Standard
16.5.2019	Head of biomedical technology department	EPSHP	Standard
16.5.2019	Product service manager	Serres Oy	Standard
16.5.2019	Head of radiology maintenance	EPSHP	Standard
21.5.2019	Technical product specialist	Serres Oy	Standard
4.6.2019	Head of biomedical technology department	ENDO -HELIOS klinik / VAMED Hamburg	Standard
4.6.2019	Head of biomedical technology department	Marien krankenhaus Hamburg	Standard
4.6.2019	Workshop manager	Greisen Product service Hamburg	Standard
4.6.2019	Founder & CEO	Greisen Product service Hamburg	Standard
4.6.2019	Head of biomedical technology department	Amalie Sieveking krankenhaus Hamburg	Standard
10.7.2019	Head of device life cycle management	HUS	Standard
10.7.2019	Head of strategic technology development	HUS	Standard
6.8.2019	System specialist	Philips Healthcare	Standard
25.4.2019	University teacher	TUNI	Discussion
2.5.2019	Medical device specialist	EKSOTE	E-mail
4.6.2019	Workshop manager	Greisen Product service Hamburg	Discussion
4.6.2019	Service engineer	ENDO -HELIOS klinik / VAMED Hamburg	Discussion
11.6.2019	Technical product manager	Serres Inc. USA	E-mail
13.6.2019	Global service manager	Serres Oy	Discussion
26.6.2019	Product manager	Serres Oy	Discussion
27.6.2019	Product manager	Serres Oy	Discussion
10.7.2019	Head of biomedical technology department	HUS	Discussion

As seen from table 5, the interviewees include people from Finland and Germany. The international pool division is 15 interviewees from Finland and 8 outside Finland to represent the international aspect. On the other hand, there are 7 case company's specialists and 3 biomedical engineers from Serres' contracted service providers to even out the inside-outside-organisation division as there are 7 biomedical hospital or service engineers from Finland and 5 biomedical hospital engineers from Germany interviewed. In total there are 23 interviews. This interviewee pool will provide valuable information and when combined with the background knowledge, provide excellent basis for development of the model of productized service life cycle.

3.2.1 Themes

As the interviewees consists of two different type of information holders: Serres personnel and customer organization personnel, two different sets of themes were created. These themes are guiding the interview towards finding the valuable information the interviewee is holding. Roughly they consist of similar beginning and end. In the beginning basic introductions are made with at least name, title and job description. In the end the interviewee is thanked and asked if something was not properly discussed during the interview. The end also includes a retouch after few days to formally confirm the interviewers notes with the interviewee's agreement. The difference is in the actual interview goals: to find out what basic services are expected by customers and what services is Serres Oy providing currently. The basic two theme lists are pictured in figure 12. Additionally, a basic structure of the interviews is portrayed in appendix B. The structure provided support for the interviewer and cohesion through the interviews.

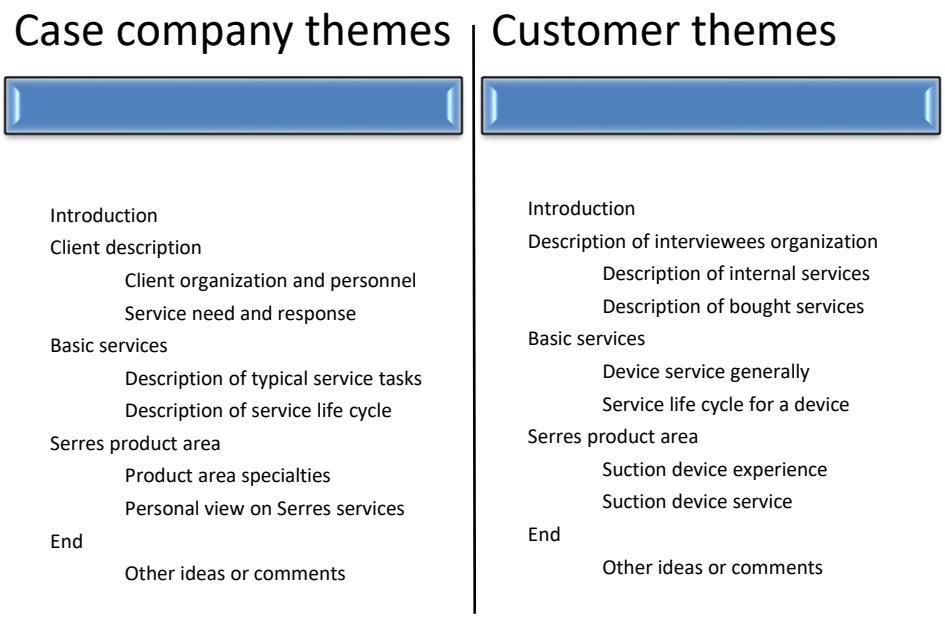

Figure 12. *Interview theme progression*

As described earlier, the difference of themes for different information holders is in great role when preparing pictured themes. In the end these themes are still just themes: they provide a guideline and support during the discussions. These themes were partially followed during the non-methodical interviews.

3.2.2 Research execution

Executing the research started with contacting possible interviewees. There were multiple persons that were contacted and eventually 14 formal interviews were conducted. The pursued contacts started within case company's organisation and was continued outside it. All the case company's pursued interviewees in Finland were eventually interviewed. First interviewees outside the case company were found in Seinäjoki central hospital medical technology department staff: the director of whole medical device maintenance technicians; head of radiology device maintenance, and head of patient monitoring device maintenance. Additionally, from the Helsinki University Hospital (HUS) two managers were interviewed: the development manager and manager of device life cycles. Later, five interviewees were contacted through case company's contracted maintenance partner in Germany: the head of medical technology department in Evangelisch Amalie Sieveking-Krankenhaus (Ev. ASK), the head of

medical technology department in HELIOS ENDO-klinik Hamburg (HEK), the head of medical technology department in Marienkrankenhaus Hamburg, founder of medical device service provider Greisen Produkt Service GmbH and the head of workshop in said service provider. The last interview was held with a system specialist of patient monitors in Philips Healthcare Finland. There were multiple discussions with service experts from United States of America and Finnish hospital service personnel as well as different experts to provide supplemental knowledge along the interview round. There were seven cases of long person to person discussions and two cases of e-mail conversations. These 9 instances are counted to the final interview pool. Even though they were not properly documented as semi-structured interviews, the information they provided had significant value and thus they are mentioned here. Towards the end of the interviews, a saturation effect of the information was clearly seen. Together with specially selecting the interviewee pool from different levels of the service chain, from the manufacturer to the end user, the information gathered was comprehensive. The whole experience of both acting party and the receiving party were adequately described.

The setting of a timetable for the interviews proved to be challenging. The possible interviewees outside the case company had understandably a casual viewpoint to an extra activity like a thesis interview, thus the initial goal of conducting the interviews during May was not reached. The last interviews were conducted in June.

The interview situations were at first tense but as the process progressed the researcher learned the tricks to relax the situation and the interviewees became more open. The predetermined themes were followed through the interviews with an appropriate amount of flexibility as the appendix B shows. As the interviews were recorded, the memo writing could be done afterwards. The interviews were not transcribed from word to word, but more written as a memo to summarise the contents. All interview memos were eventually approved by the interviewees as it is the good practice.

Overall the research execution progressed well, and major failures were avoided. Naturally there were lessons learned during the process for example how to socially handle different people and cultures, how to find the information wanted, how to actually conduct the interview and how to write fitting memos of the interviews. The goal of defining the essential service elements was still adequately reached.

3.3 Method reliability assessment

Reliability is an important aspect of scientific research. It reviews the research process from the data gathering method and the original source to the analysis and conclusions. Reliability discusses if the results can be thought as scientifically valid. The validity could be described so that with similar method and premises, someone else could repeat the process and end up with similar results. In qualitative research the repeatability is not as unambiguous as it would be with quantitative research. This chapter mainly considers the reliability and redundancy of the research method in this study.

The saturation effect in research results is a natural and strived element. It is even designed into the process of reliable qualitative research (Pickard 2007, p. 14-18). In its essence, saturation means that new information provides little or no change to the data set (Gubrium 2012, p. 347-367). This effect was clearly experienced during this case study. The interviewees constantly pointed out the similar aspects to the questions asked and by their own initiative. The e-mail- and discussion interviews contributed to the same effect, which was a clear indication to include these cases to the interview count. Generally, saturation is an ever-closing loop toward a conclusion or a result.

Saturation cannot be thought as a self-evident proof of accuracy of the results, only of the results pointing to the same conclusion. After realising a trend of saturation, the source material must be evaluated. Here the source material is the interviewee pool. If the source is too homogenous, the saturation point is skewed towards results affected too much by the source premises. This enables false conclusions. It is detectable from table 5, that the backgrounds of the interviewees in this study range distinctively. There are interviewees from private companies and state-run entities, manufacturer service and service receiving parties, Finland, Germany and USA residents, management level and hands-on performing employees. The interviewee pool is not homogenous, and it is appropriate in order to reach the goal of this study.

There exists deviation in the definition of the saturation between different sources. They are minor in the sense of how it is detected and how it addresses reliability. It seems though, that the consensus is that saturation effect is a natural and sough effect in qualitative research. (Gubrium 2012, p. 247-367) The detection still, is either an empirical finding, or statistically proven. The statistical method with its mathematical nature would be more scientifically sound, but because of the low sampling (n=23) in this thesis, it is not possible. Thus, the saturation is detected by the researcher personally in this research. In some interview-based studies a second round of interviews were held, or a

control group would have been established. These aspects would have increased the reliability of this thesis tremendously, but the resources are limited. These aspects were considered, but quickly abandoned.

Overall, this thesis finds a saturated trend in the interview results with ranging source of information. Even though the qualitative results cannot be statistically proven to be true, it is justified to state that the results are reliable in the scope of the thesis application. The research results are presented in the chapter 4.

4. CASE STUDY RESULTS

This chapter dives deeper to the case company's business environment regarding the research and the interviews. On the results of interviews different aspects of customers are analysed and opened for discussion. The main themes of interest are customers themselves and customer life cycle needs. On the other hand, product life cycle is in the centre of customer needs and must be considered. This chapter provides the research results to integrate the theoretical background with when creating results in chapter 5.

4.1 General presentation of case company customers

It is clear after the interviews, that Serres Oy customers consist of different hospitals. The provider-customer network withholds also the contracted international distributors and service providers as well as the local regulative authorities. The interesting parties inside hospital organizations are the biomedical technology department and the end users. According to the interviews in Finland and Germany as well as the discussions with experts, the end users are mainly operation theatre nurses and hospital hygienic staff. Although suction devices are made available virtually in every department of a hospital, the use is focused in surgery wards. During surgeries it is the aiding nurse that is responsible for providing the doctor a line of sight to the centre of operation with liquid and the collection of said liquid. Later, it is usually the hospital hygienic staff that is responsible for handling the collected liquid waste and cleaning the operation theatres. Complementary to the use of devices, the devices must be maintained and managed. The biomedical technology department is responsible for this. The department usually is in control of thousands of devices and they have responsibilities of documenting and maintaining their state of function. The capabilities for maintenance between different biomedical technology department organizations in hospitals is vast. They span from exclusively management-oriented organizations to organizations that have also competence in maintaining the devices. The span between these two points includes all the different variations, or shades of grey, of orientation from outsourcing all the maintenance tasks to maintaining skilled service personnel in their own organization, as seen in figure 13. This research pointed out that the culture differences are huge even between otherwise so similar considered Finland and Germany. Thus, the differences can only be expected to be from completely other dimensions when studying even greater culture differences. This is what the figure 13 strives to emphasize.

Organization only for management

Organization with service capability

Figure 13. *Variety in hospital biomedical technology organizations' capability of maintenance*

The variety became visible during the interviews when comparing the organizations of HUS and HEK Hamburg. In HUS they had tens of skilled service personnel to provide them immediate service. What is remarkable is that these service personnel are trained by the manufacturers to provide basic service to the devices, naturally depending on the complexity of the device. In HEK they had only one person responsible for management and documentation while virtually all the service is outsourced to private service providers. The local regulatory authorities are influential in virtually all decisions regarding the device: they regulate the certificates required to be authorized for certain type of maintenance; they supervise that the people using these devices are trained properly; where they have financial interest, they see that the contract tendering is performed as it should be. This was clearly the case in Finnish and German hospitals, and it is noteworthy that these cultures are somewhat high in normative aspects discussed in table 3.

As figure 14 shows, the business environment of medical device providers and hospitals can be generalised to a certain level. The manufacturers can directly operate the full product-service portfolio with the customers *i.e.* hospitals. This requires significant organizational power in maintenance and distribution, since the cultural aspects in global environment are colourful and demand different culture related actions such as business etiquette. For this reason, most medical device manufacturers have distributors in different market areas. They have their own provisions on sold units, but they have the networks and social know-how to conduct business instead of the manufacturer. To support the sales and devices, there must be service providers available with adequate skills in these areas.

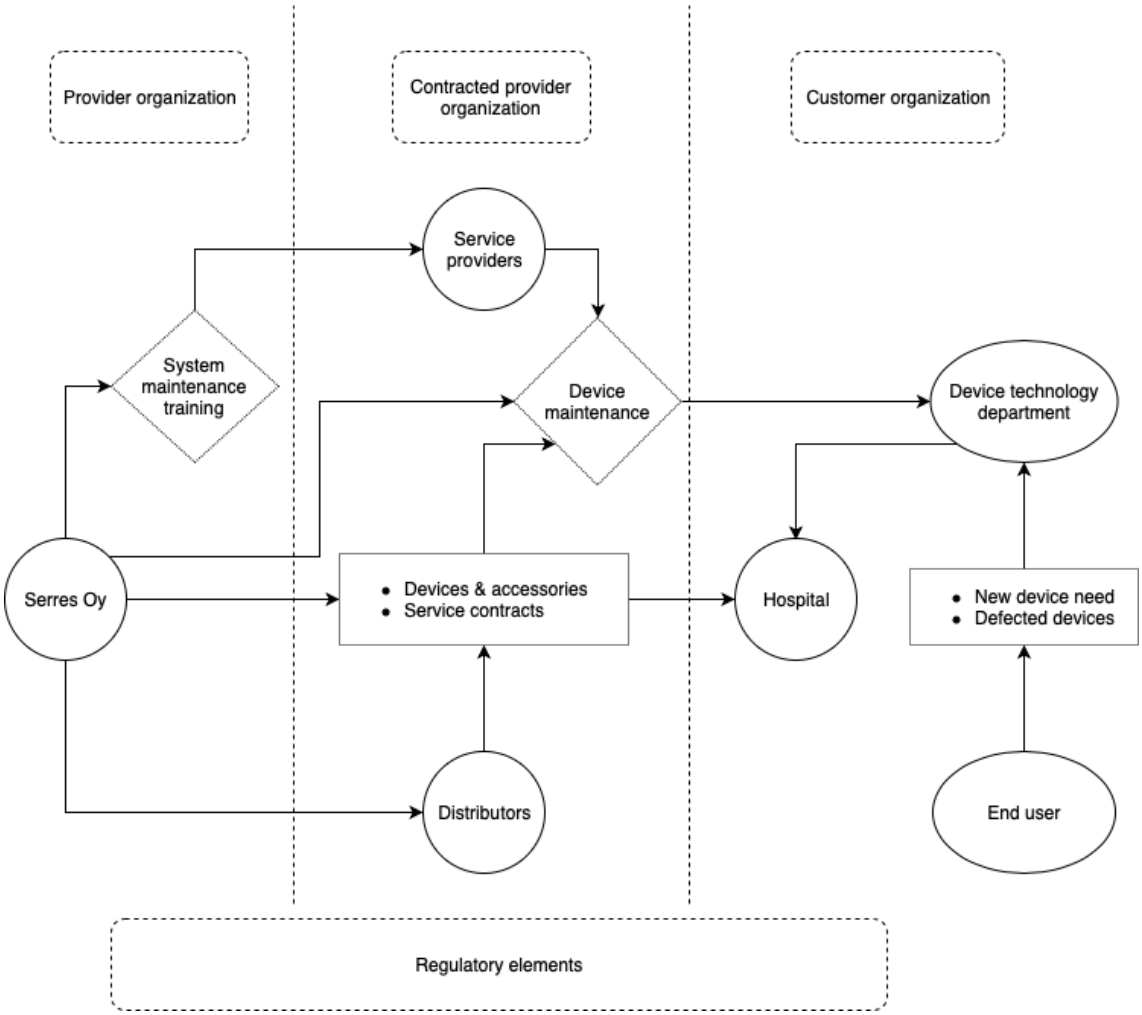

Figure 14. *Simplified business environment*

In its essence, the business environment is pictured in figure 14. According to the interviews this basic model applies directly to Finland and Germany. With minor adaptations this model can be adapted to picture the rest of Europe.

4.2 Analysis of customers' needs in product-service life cycle

The needs of Serres Oy customers aren't insurmountable. In its essence it is quite simple: hospitals want to maximise the utilization of the devices in order to provide safer and more efficient care for the patients. This occurs in all the phases of product-service life cycle.

In the beginning of the cycle the purchasing department organizes an acquisition group, consisting of the different parties involved such as financial power and responsibility, end users, biomedical technology department and IT. This group strives to ensure a device with certain specifications such as proper functioning, adequate maintenance contract, and a price in their budget. A specific financial term that was widely discussed in the interviews with customer side was Life cycle cost. Hospital financial staff seems to have adopted a way of analysing device costs through its whole lifetime. As mentioned in chapter 2.3, LCC is a comparable financial statement between competing products for the total costs related to their life cycle. The contract also withholds a warranty time that seems to have normalized in EU to one year, except in Sweden this duration is two years. During this warranty time usually all defect and scheduled maintenance is included in the cost as well as the training of the staff. The type of training varies. In Germany there are “heads of training” in the different departments that are trained by the provider and they further take care of training rest of the staff. On the contrary, in Finland the provider usually provides the training for all the end users. Before customer can start to use the product, it also must be installed. This is the providers responsibility in the span of at least preparing the device into a condition of use, depending on the type of device. Additionally, the local regulatory elements have standards, that need to be proved fulfilled. This might be provided as certificates of conformity and demonstrated safety checks. When all this is completed the customer may start to operate the device.

When devices are operated, they will have defects. These defects require maintenance. The hospitals need defect maintenance and scheduled maintenance in order to maintain their devices in a state of functioning. Depending on the type of contract, these might be included in the time of warranty. At the end of warranty time, there is a contract review between the parties in the contract. There the different clauses of the contract are reviewed, and proper actions are taken. There might be contractual penalties before the provider is released from their duties held by the contract.

Depending on the location and culture, the contract might also contain a third-party service providers recommendation by the provider. It was clear in the interviews as explained in figure 13, that biomedical technology departments operate with different capabilities of service. This service provider is then at least recommended to be used when in need of external service. All the interviews mentioned the need for phone support in basic maintenance. The technical expertise is impossible to hold for thousands of devices inside a hospital. This phone support is expected to be fast and agile, but

reasonably reachable within office hours. Maintenance is often accompanied by spare parts. The spare parts should be available fast, and the ordering process should be quite straightforward. The service personnel should be able intuitively or with a manual to order the right parts. This use period is expected to last until the lifetime is fulfilled. Usually providers engage into supporting their device for the duration of life expectancy. Support generally means to provide services such as technical phone support, spare parts, maintenance, and updates, for a price of course. There might be a contract clause of best effort support. After the expected lifetime the provider engages to really provide their best efforts in order to maintain the customer device state of function. Best effort means that there are no real guarantees or responsibilities of available services.

In the end, there is the abandonment phase. Here the device has broken down or is needed to be replaced by better technology. According to the interviews it seems that the abandonment starts from an initiative by the end users or by the technical department, seen in figure 14. The end user usually experiences a fatal defect in the devices, when the technical department might notice that the device is significantly old when arriving to maintenance. Then the technical department evaluates the cost of maintenance, cost of a new device, and the possible future costs related. Based on all these experiences, a review inside the hospital is conducted and an abandonment decision reached. Firstly, the hospital needs to recycle the device. They usually pay according the local recycling process and receive the service from the local recycling entity. There exists a possibility of compensating the hospitals for sending the used device back to the provider to be reused. Secondly, hospitals are in need of a new device, so the sales process must be started again. Combining these two, the provider might compensate the hospitals for old device when buying a new device. This way the customer can be retained in the company customer portfolio. These needs have been drawn out in figure 15 and for the sake of the shape of the figure it has been turned sideways.

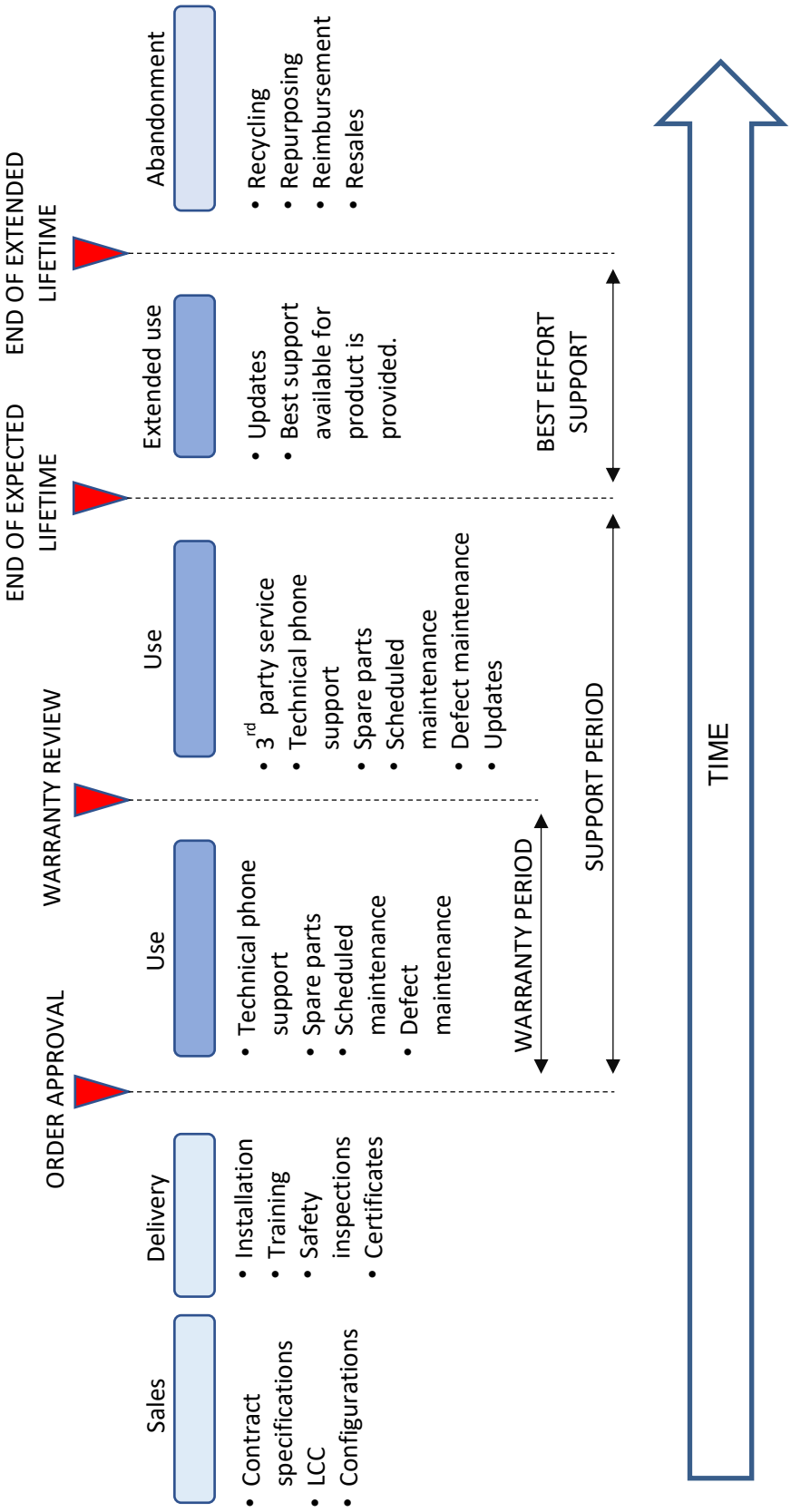

Figure 15. *Interview results on basic service life cycle needs*

When figure 15 is inspected laterally, the time travels from left to right. Over the red triangles, there are important milestones in service life cycle such as order approval, warranty review, end of expected lifetime, and end of extended lifetime. These milestones part different steps of service life cycle from each other. Under each step there are listed basic service needs in during this period and the relevant terms are visualized and placed in their correct place on the timeline.

In addition to the life cycle needs, there were some remarks during the interview round that were notable. More related with the service needs, there has been a significant increase in different PSS when regarding medical devices in hospitals. The types of PSS include monthly subscription devices, where the hospital pays a certain amount for the device, its consumables and a level of maintenance. There also are devices with pay-per-diagnose model i.e. the provider makes sure the device is in state of functioning and the hospital only receives the value of the process for a fixed pay-per-use price. At least in HUS they have multiple devices with this kind of contract, but this is to be expected, as HUS is regarded as the most progressive university hospital in Finland. In HUS they have also noticed the rise of medical devices connected through a network. According to a rough estimate in the interviews, as much as 40% of the devices are connected through a network in a way or another. This number includes at-home monitoring devices and patient monitors, but also devices connected to internet in order to be maintained, monitored and updated through internet. More culture related notes were drawn on the language requirements: the end users might have a limited range of language skills, or they might even lack the local language totally. This is the result of recent shifts in social and economic politics in healthcare.

The Serres product area was considered just as a low-maintenance part of the hospital biomedical device technology departments' responsibilities. The main issue is reliability. The suction must be available when needed for patient safety and operating surgeon visibility. In every interview the greatest concern for suction equipment failure was the possible central vacuum system. Hospitals have a central vacuum system providing suction from a socket in the wall. There exists a significant risk for the suction equipment failure and the liquid waste entering the central vacuum system. If this risk is realized, it demands a comprehensive disinfecting operation. In addition of costs in the disinfection, it also renders the central vacuum system partly or totally unusable for a period of time. The operations then are carried out with weaker vacuum pumps. This scenario is the main speciality, or concern, in Serres Oy product area through the interviews.

5. PRODUCTIZED SERVICE LIFE CYCLE MODEL

This chapter aims to combine the results gained in the research with the theoretical background information in order to create a proposition of a productized service life cycle models for medical devices, especially for the case company. The emphasis is on answering especially the following questions. What services could be productized and how should it be considered in medical field culture? How should this be considered in the case company's product-service life cycle and what value will it bring for the customers? Visualization is pursued to be performed with different model figures.

The requirements for this model have been created in co-operation with the thesis guiding group. This proposition of a model strives to provide support in decision making and concept creation for service and product managers of the company. The model shall convey visually and by text a broader picture of service needs and service factors in customer – provider relationship as well as a propositional model for profit gaining through providing value for the customer.

This model has been divided to two distinctive parts: service life cycle model and PSS categorization. They provide different information for different use, but the goal is that combined they create a wholesome concept of service and business without too much discussing the organizational needs. The PSS also includes methods to modernizes the pricing method of medical device product service combinations

As mentioned in chapter 2.3, life cycles are formed of different phases, which have their unique characteristics in needs and trends. The essential services are presented in figures 9 and 15. Figure 15 also implicates of the cyclical nature of customer relationship that provides the basis of fruitful provider-customer -relationship. The combinations of different types of services and productization of the repeatable elements mentioned in chapters 2.1.1 and 2.1.2 are brought to light also in the life cycle model as an option for remote diagnostics. Automated diagnostic software run remotely will provide a basic start point for any device manufacturer in maintenance. The life cycle is divided into 4 phases for the sake of more general utilization as it seems most medical devices have at least corresponding phases in their life cycle. This LCM consists of the phases named here sales, warranty period, use, and recycling and they all are presented in the form of service blueprint introduced in chapter 2.3.2.

The PSS is quite straightforwardly based on the results of the research and chapters 2.2.1 and 2.2.2. The service elements are seen to provide value in the customer process and as seen in figure 15, the customer processes differentiate in the scope of capabilities as well as on cultural aspects as explained in chapter 2.1.3 and 2.2.3. This creates a need for different inclusion, or levels, of service elements in the PSS. Also as shortly is described in chapter 2.2.2, the method of profit gaining can be viewed through utility or value gaining and thus a proposition is provided based on the research results.

5.1 Service life cycle model

In its essence service life cycle model strives to point out the essential service actions during certain event. These actions revolve around customer experience and the physical evidence related, which in the end creates experience factor of good service. Good service experience then again leads to releases and prosperity. In Serres Oy the service organization is being developed and this proposal is used as a tool for decision making as a second opinion or an outsider view. The researcher has limited knowledge and experience of the company and the medical device service field and thus has the potentiality to point out unthought aspect, to provoke new ideas or to widen the field of vision.

With the support of theoretical knowledge, typical phases of life cycle were identified for medical devices. They include four phases: sales, warranty period, use, and recycling. With this kind of breakdown, the phases are general enough to not be applied as process models for certain events but detailed enough to separate into clear phases. The sales phase starts the cycle with customer need, which is essential for any business transaction, and ends in the approval of delivery. The warranty period starts here to last for the span of warranty time and to end with a formal warranty review with all the stakeholders being present. Use period spans from approved warranty review until the end of device life. The last phase, recycling, starts with the device being obsolete and ends when the individual parts or the device have found a new purpose. The phase between device end of life and device being obsolete is a unique event, which is usually called best effort period. This period is not repeatable and thus is not included as a phase in the lifecycle

Within the service providing organization, there are multiple actions and roles on different levels to focus the required actions. The levels are separated with a line of interaction, which is the border between a customer and a provider, a line of visibility, which divides the actions seen and unseen by a customer, and a line of internal

interaction, which implies that the service organization is reaching to different department within the provider organization. Within the figures the leading actions are connected with arrows to underline their importance. The related actions are simply connected via lines to provide a sense of continuum in the figure. There are elements that are connected or surrounded with dotted line. This dotted line implies that there are certain conditions for these to occur. For ease of inspection, all these service blueprints can also be found as appendixes from C to F in the end of the thesis.

The first service blueprint considers the sales phase. The essential path spans from the risen need for the device to the approval of delivery. This path is accompanied with the relating supporting acts. The main concern in this customer path is the line of interaction. The communication between customer and provider all the way to the installing engineer needs to be continuous. This continuous stream of communication guarantees that the customer needs are properly seen to be fulfilled. Fulfilled customer needs lead to returning customers and less unique actions down on the service life cycles other phases. The supporting acts mostly consist of CRM event documentation and contract management. These acts continue through the whole life cycle, but their nature demands for highlighting the most critical moments. According to the interviews, it is too easy to forget or neglect this kind of supporting actions during the process. The sales phase service blueprint is shown in figure 16.

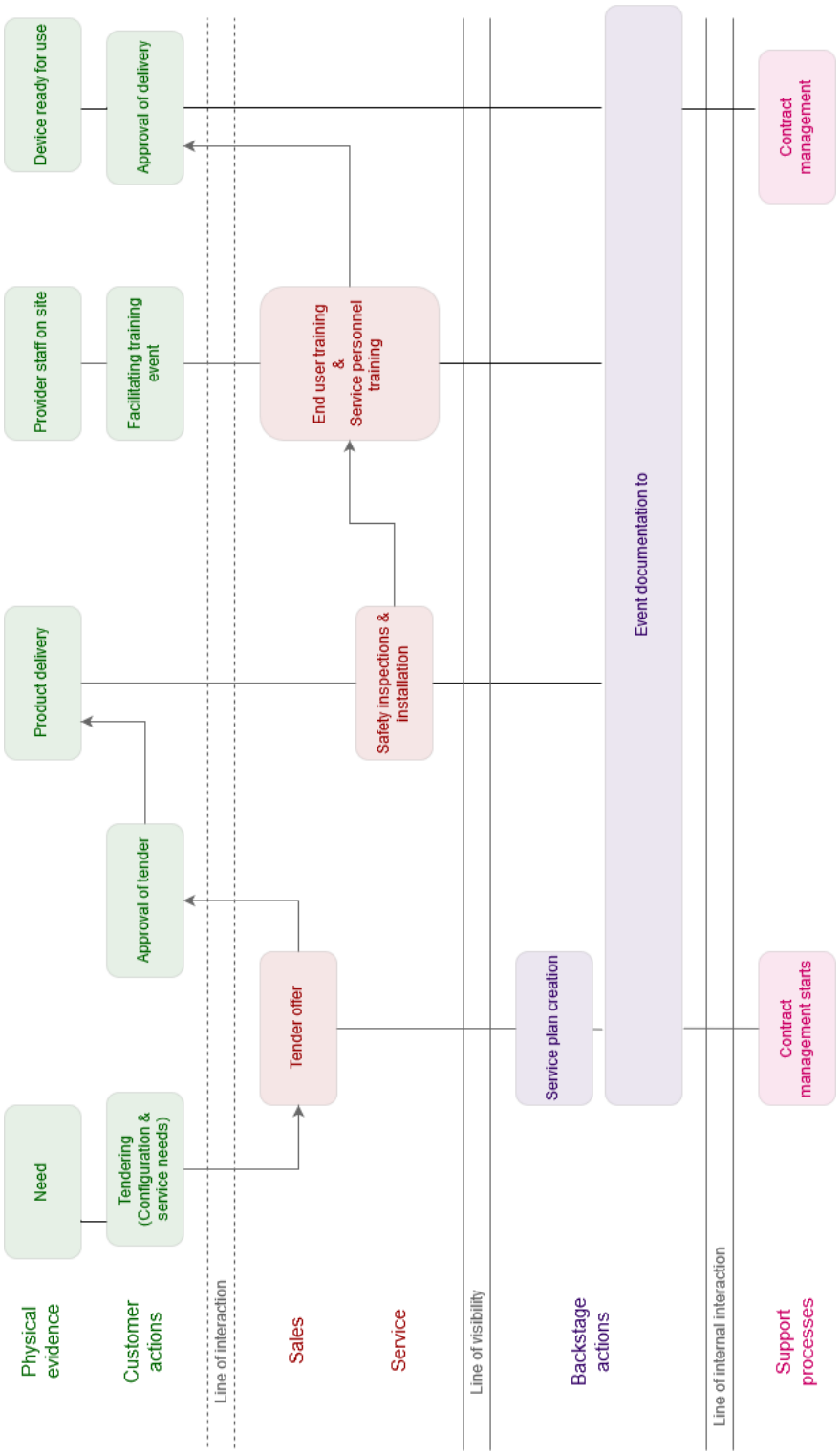

Figure 16. *Sales phase service blueprint*

Sales phase, and the whole life cycle, starts from the customer need for the device. Beyond certain amount of expected spending, most of the sales are done through tendering. Any provider can make an offer to the tender, and the offers are reviewed and scored according to specific standards, mostly money and time ruling the sheets. After successful tendering a contract is reached and the device itself is delivered. It is expected that the provider installs the device. This ensures the safe use of the device, or at least decreases the risks of device use. The customer might also require the manufacturer to provide the safety certificates and authority satisfying documents at the installation. This aspect is coordinated with the contract and the biomedical staff inside customer organisation. Before the device can be used at site, the staff must be trained. This happens according to the local culture, but the details are usually listed in the contract. After successful training and fulfilment of contract terms, a delivery review is held. Once again, the contract terms and their fulfilment are reviewed. If all is well, the customer approves of the delivery and the warranty period begins.

In the beginning of the sales especially contract management must be an active supporting task. The contract is the most important aspect in this phase, and it defines much of the future too. Naturally the events relating to customer contacts shall be documented correctly to the CRM system.

The next phase of service life cycle is the warranty phase. The ideology is that virtually all medical devices have a warranty period. It usually spans one year from the approval of delivery. The warranty phase ends with warranty period review. During this review the fulfilment of different contract terms are reviewed, and the provider is relieved from most of their responsibilities. The warranty period holds different service terms than the following use period, usually the warranty period covers all defects except user originated ones. The figure 17 consists of two different main paths: remote diagnosis and user-oriented defects.

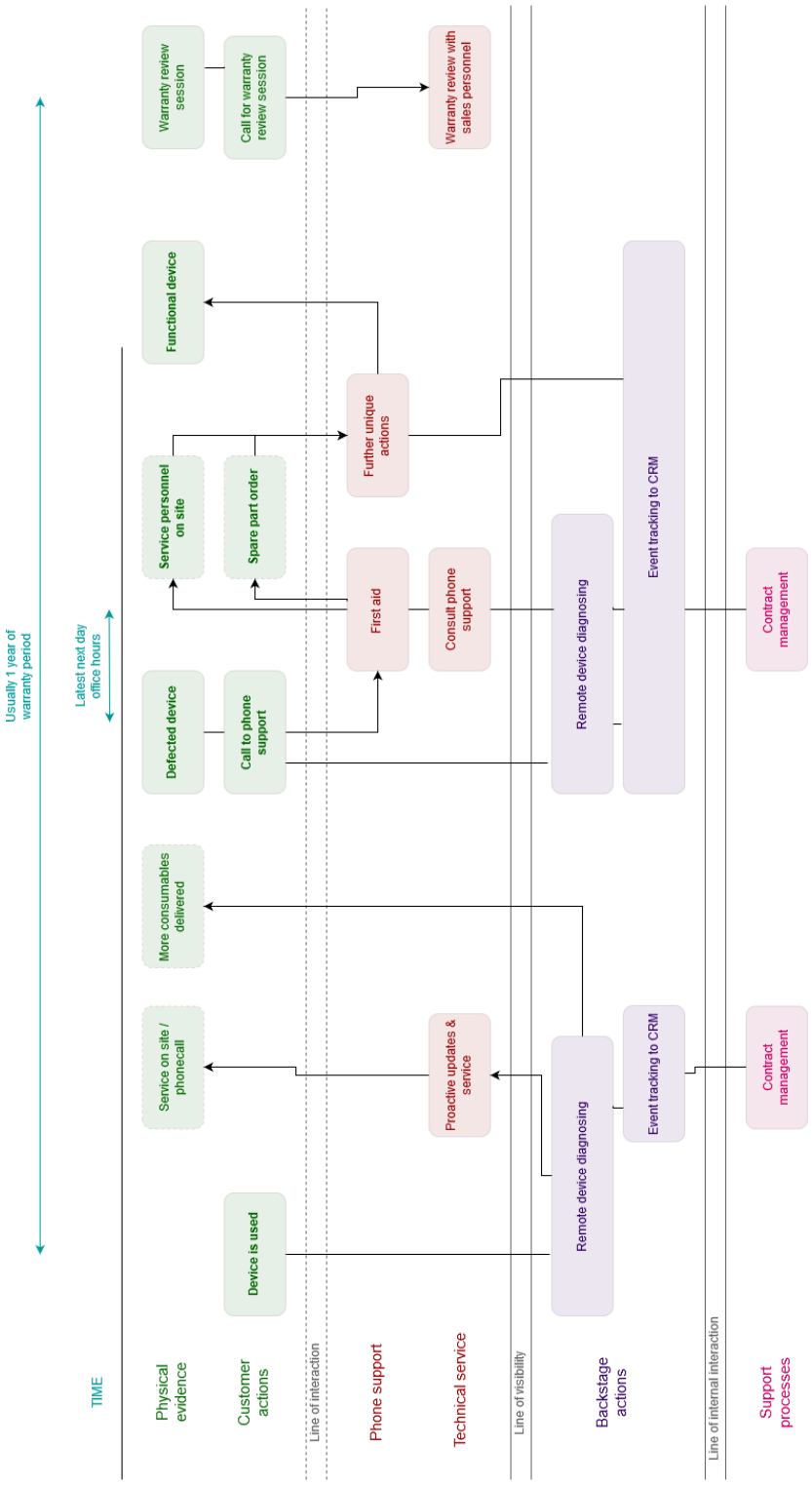

Figure 17. *Warranty period service blueprint*

Warranty period consists of two main paths. Both are ongoing and overlapping, but for clarity pictured successively. The remote diagnosis path is the result of proactive service strategy, that manifests itself as predictive action. The actual state of the device is diagnosed via a remote defect diagnosis tool. The tool should measure the technical capabilities as well as read the time and amount of use to predict wear down. Technical expert shall read the report and decide on the actions. Depending on the type of contract, this diagnosis tool could also be used to send out consumables or other necessities. The remote diagnosis is supported by contract management to reassure the terms on the contract and the CRM documentation for R&D use as well as customer relationship use. The remote diagnosis should be integrated in a way or another to the scheduled maintenance plan. Scheduled maintenance is included in the warranty and provides a preventive service action. The remote diagnosis could be run just before scheduled maintenance so the results can be acted on during the service visit that is coming anyways.

The other path is the user-oriented defect. In this case the remote diagnosis tool has failed, or the defects is a sudden defect during use. This leads to the customer contacting the phone support of the provider. There the first aid is given to the problem either as a service support solution, or as a promise of further service. The proper action is taken, and in the end, the customer has again a functioning device. This is reactive service. The warranty period ends to the warranty review. There the warranty period and the contract fulfilment are reviewed. Penalties might be ordered, if there have been significant problems. Otherwise, the customer approves of the warranty period being fulfilled and the life cycle continues to the use phase.

Use phase is the longest period in service life cycle model. It spans from the end of warranty to the end of life for the product. Usually the lifetime for a medical device is expected to be somewhere around 10 years and consists mainly of the normal use of the device. This lifetime of a device is defined by the manufacturer and usually this timespan also holds a promise of support for the device. After the use phase there could be stated to exists a period of best effort support. During which the manufacturer does not promise to maintain support like spare parts and service personnel but promises to provide their best effort to provide these. Similar to the warranty phase, the use phase consists of two controlling paths. They differ mostly by the scope of included services, as the warranty period is usually more inclusive with the variety of defects. Figure 18 pictures the use phase.

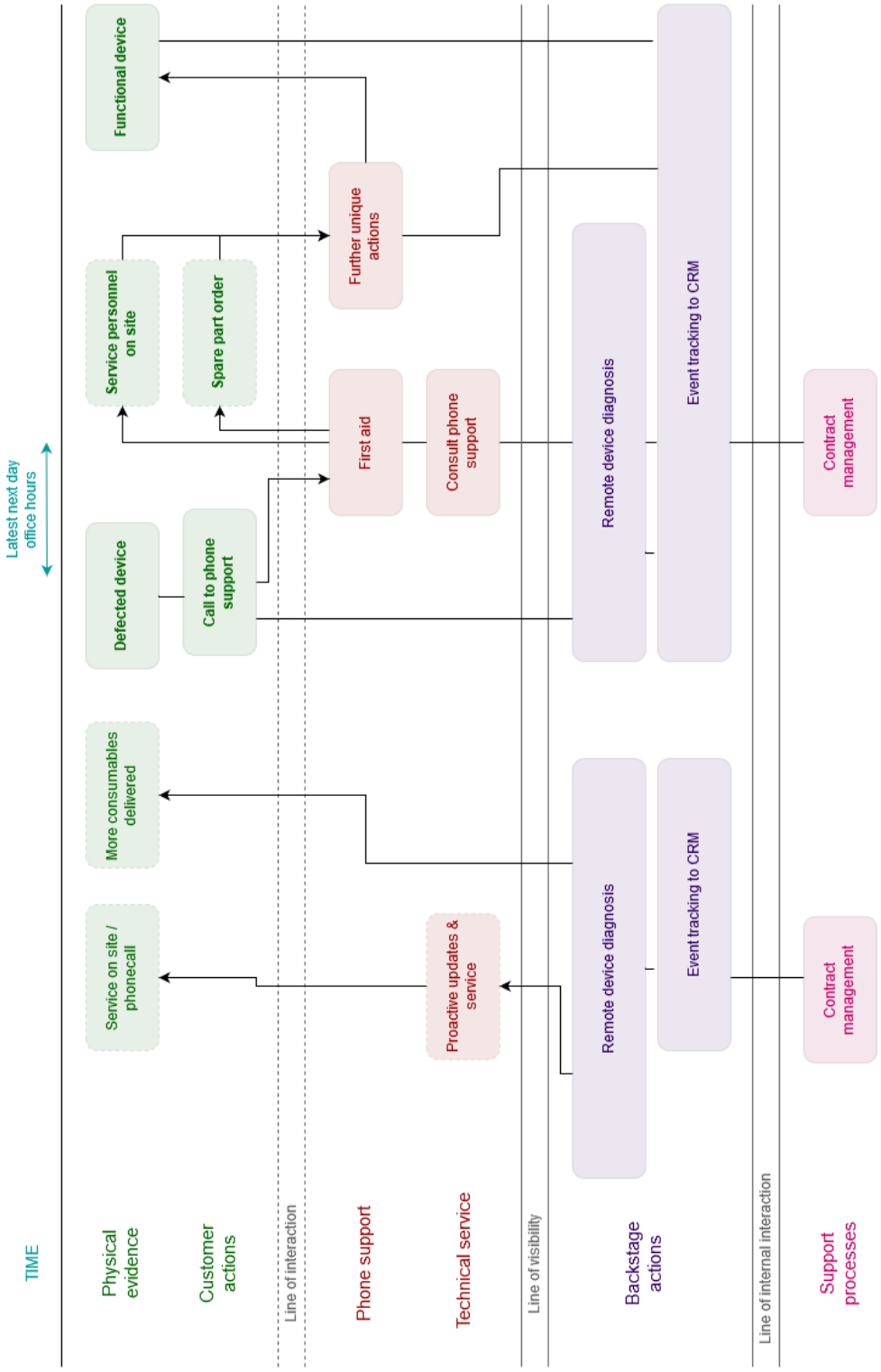

Figure 18. *Use period service blueprint*

Use period is exactly similar as the warranty period in figure 17, but naturally doesn't end in warranty review. Use phase differs from warranty phase in the inclusion of service. During warranty virtually all defects are free and included in the warranty, with some exceptions of user errors. During the use phase all service, except manufacturer errors, are under the service contract. Manufacturer errors must be corrected, but other cases are actioned upon according to the contract.

There are only few time specific actions that were mentioned in the interviewees. The most important one is the phone support response time. The phone support must response in a way or another at latest during the next office day. This applies to all contacts, be it a defect case or customer guidance, warranty period or use phase. The other time specific actions weren't reoccurring between interviews or generalizable.

Recycling phase is the last phase of life cycle service model that a device sees. It starts with the customer recognising their lack of need for this type of device and ends in the full or partial reuse or recycling of said device. The essential path here follows closely the customer – provider line of interaction where the communication is again in a central role. This path is supported heavily with CRM documentation and contract management as the goal is to maintain this customer in the customer portfolio of the company. This is visualized in figure 19.

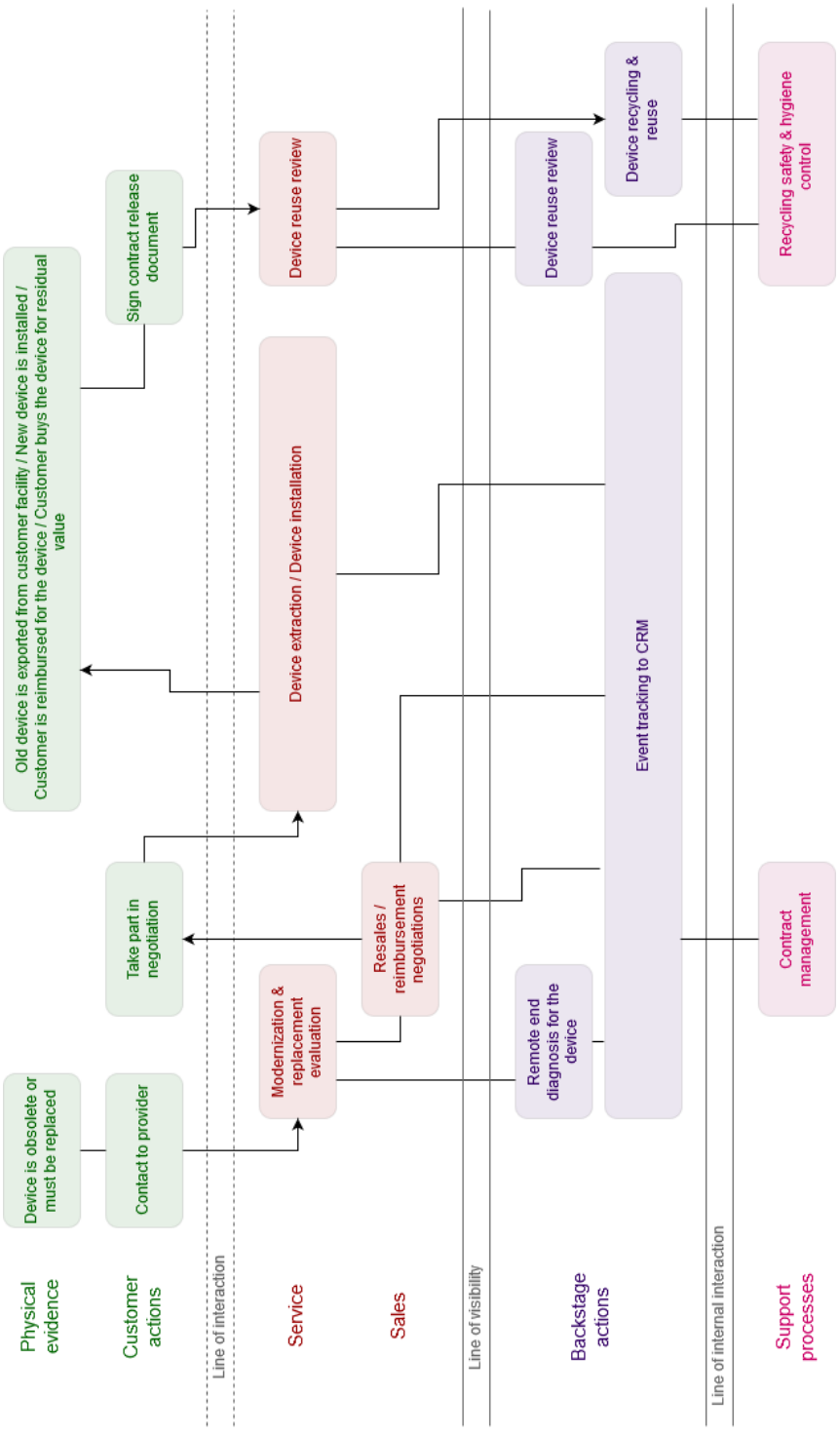

Figure 19. *Recycling phase service blueprint*

As mentioned, the recycling phase starts with the customer experiencing the lack of need for this device in its current state. Either the customer will contact the provider, or a functioning service and sales team will recognize this state of redundancy. This leads to service personnel to scan the device state and in co-operation with sales team to create a modernization plan. This plan will consist of either updating the device to renewed customer needs, planning a new type of contract for the device, or other applicable solution. This situation is negotiated with the customer back and forth until an agreement is reached. Whatever the solution eventually is, shall be promptly executed. Execution continues up to the point where all the former agreement documents are ensured to be in order. This is an important part of CRM and contract management for the possible hindsight problems that a customer can claim are damaging. Inside the company whatever parts are decided to be recyclable, either to spare parts or just environmentally properly, shall be handled with proper process. This process might include steps like hygienic clearance, memory wiping from computer-like parts, and documentation. A well-founded process and documentation reduce risks of any errors in future products. A well-founded process is up to the current state of the globe and ever better, relevant public relations material. Public relations will eventually become a problem of sorts for any plastic single-use product manufacturer, be single-use plastic product the optimal solution or not.

This model provides a complete life cycle service model. It includes reactive, preventive, predictive and proactive elements. Additionally, it strives to leave room for cultural aspects as well as the unique actions that service usually is. The entity is a summation of the case study results and the theoretical information provided during this thesis. It provides a broader picture of the service landscape: What is essential in service, what is valuable for the customer. When integrated with PSS development, this model provides a modern view on the medical device service.

5.2 Product-service system concept

The basic idea for product-service system is to provide a utility instead of ownership, as explained in chapter 2.2.2. Moreover, there can be multiple different PSS bundles in a company’s portfolio for different customers. The need for different bundles arises from variance in the company, business and local cultures, as is explained in chapter 2.1.3. Since it is apparent from the research that hospitals have different culture for organizations and their capabilities in service, there must be adequate variance in the company portfolio of PSS.

The underlying idea in the PSS concept is not of bad service to basic service to the premium service. There is no sense to deliver bad service to customers. The idea is to identify the elements they need and fit to their service culture. This is what figure 20 tries to embody. There are different PSS categories with set of service inclusion the most fitting for clients that need full-service experience with minimal effort spanning to the culture of self-sufficiency that was experienced in Finnish hospital mentality. Naturally, it is on the company agenda to push for higher profit enabling bundles, but that is a strategic and a marketing decision. This push might in the end bound the true portfolio to a smaller set of variety.

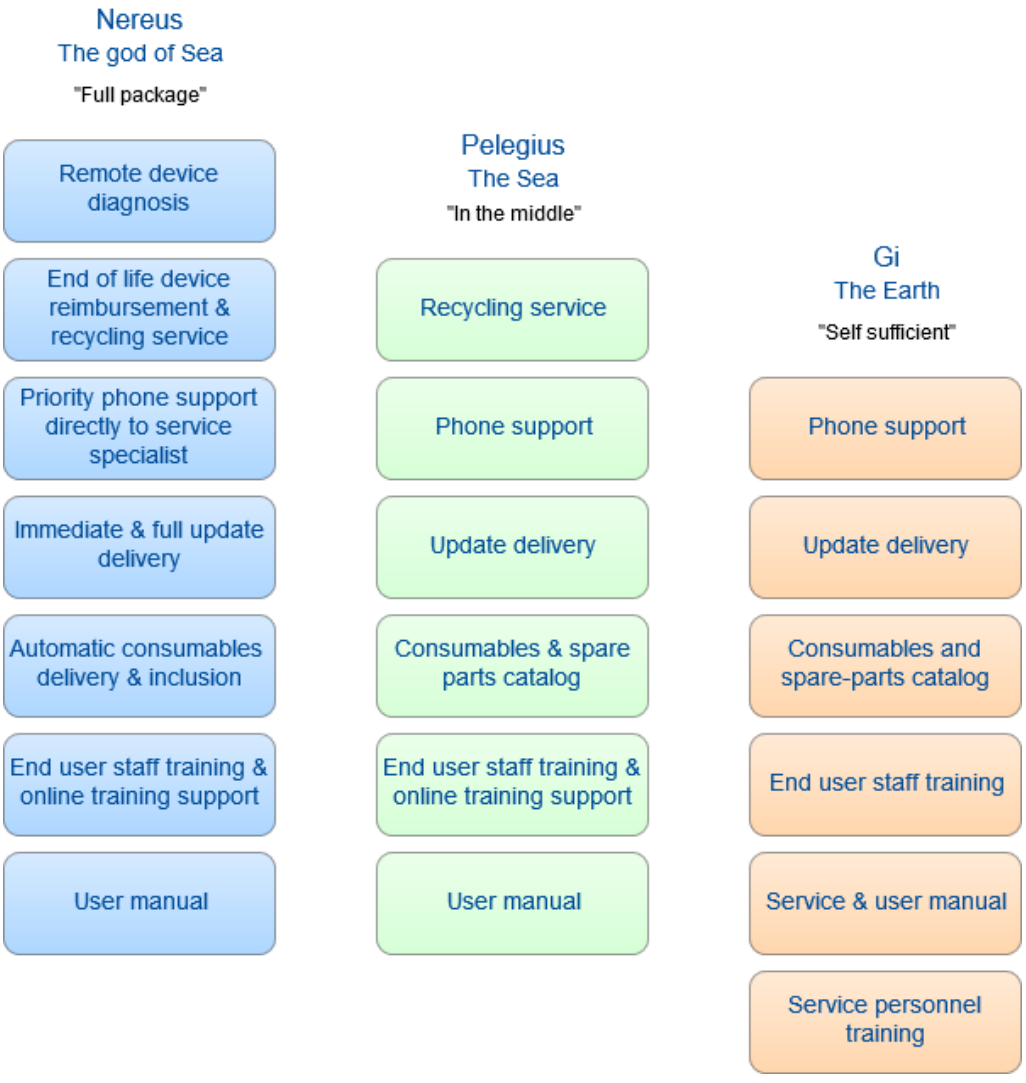

Figure 20. *PSS concept*

It is clearly visible in figure 20, that it holds three different categories of PSS: Nereus, Pelegius and Gi. These names stem from Greek language and mythology with the intention of following Serres Oy portfolio trend. The Nereus is designed to fulfil the needs of customers like HELIOS ENDO-KLINIK, that needs the full support and has no personnel to deal with the scheduled maintenance and defects. The Gi is planned to provide most value to the customers with their own service personnel. They live in a culture of self-sufficiency and it is usually their need to feel in control of the devices. In the middle, the Pelegius, is designed to stand out as the intermediate option. Whether the customer is not sure of their needs or the PSS system, they are then guided towards this option. Later the customers are helped to optimize their PSS to their actual needs.

The singular elements in each end of this spectrum serve a purpose. Naturally all the categories also include the essential service aspects such as user manual, user training or installation. Installation services are not mentioned here, since they are always demanded from the provider to ensure safe premises for the use and utility. The Nereus concept has the remote defect diagnosis option, priority phone support and online training support to provide the customer a functioning device with minimal effort and inconvenience. On the other hand, the Gi bundle is made to serve the self-sufficient organizations. That is why they are missing these options but have an option for technical staff training. It would be beneficial for Serres to push most of their customers towards the Nereus. Not just because of potential profits, but for the control of service and device states generally. The more the company is in control and aware of the condition regarding their products, the more they can gather feedback and develop their product but as well the service the devices receive is more similar in quality. This cycle of development, control and similar service increases the reliability of the devices more than variety of services. The reliability is the main concern of the end user and customers as the research states. Reliability is a long-term aspect, that epitomises itself in the service costs and eventually in the pricing of the PSS.

There are multiple possibilities for pricing with the introduced model of PSS. During the interviews it was clear that the traditional simple ownership of the device is being challenged by pricing the utility of the device. The preferred one is the subscription model. In this model the customer still buys, and is handed, the ownership of the device, but they subscribe to a monthly fee for upkeeping the device functioning. This is easier for the customer’s finance department to budget and to handle than sudden and huge single costs for maintenance. In addition, this provides the manufacturer a chance to productize their PSS while optimizing the costs and profits in the process. Customer

value is the selling point in this method and value of a functioning device is completely different from just the device. Naturally the key for this model in the eyes of manufacturer is to know and understand the resources needed for keeping the devices in a state of function. The competing concept for pricing would be the use-based model. In this model the customer is billed for the units of use. This requires remote monitoring of usage and complicates the contract management as different customers operate with different rate of use with unknown rate of support needs. These facts alone make the cost calculation for each customer unique and thus create more financial risk.

For these reasons, I recommend Serres Oy to consider updating the pricing for medical devices into a subscription model. In their case, the ownership of the devices would be still handed to the customers in all PSS categories. The category then itself would determine the monthly, or yearly, subscription fee for included services. The actual pricing and inclusion should obviously be balanced with the experienced costs and resource consumption. The pricing model would provide a selling point to the technical and financial departments of hospitals, as the budgeting is a huge load for the decisionmakers and essentially the included service releases time for the technical staff to handle cases with less complexity and higher priority. In addition, the remote monitoring for device defects would provide a proactive method to avoid severely defected devices. Updates and patches for software would be provided via internet and the future defects could be predicted with diagnosing software that could be run during the downtime of individual devices. Thus, the reactive maintenance would be limited to the acute physical defects which currently hold an undetermined percentage of the cases. This productized service model holds potential for profits if successfully utilized.

6. CONCLUSIONS & DISCUSSION

In this chapter the thesis is discussed, and remarks are drawn from the execution. Discussion pursues to provide context for the results considering other research publications and the execution of this thesis. Additionally, the execution of mentioned thesis is reviewed and possible future follow-ups are pointed out. The goal is to end this publication according to good scientific practice.

6.1 Conclusions

This thesis considers medical devices, their life cycle and services around them. The theoretical literature review is integrated with the research findings. Research in this thesis was conducted as a form of insider action research with 14 extensive semi-structured interviews and 23 instances of interviews in total. The research strived to define the essential service elements and the thesis aimed towards creating a proposition of a productized service life cycle model for medical devices. This goal was reached as demonstrated in chapter 5 and the work was performed within the planned schedule. The thesis project resulted in a justified proposition of service life cycle model and PSS concept as well as a proposal for pricing method. The service life cycle model includes essential service elements as well as the customer path integrated with respective factors in the provider organization. The concept of PSS strives to convey how different client organizations have different needs and thus the productized service bundles provide value for them equally if correctly identified. Simultaneously it is recommended to transfer into subscription-based pricing for the service of functioning devices. There are examples of this providing competitive advantage in the field. Overall, the set goals for this thesis have been accomplished with adequate results and within the timeframe. Moreover, table 6 provides a brief conclusion of most important aspects around the thesis.

Table 6. ***Short conclusion of the thesis***

Goal	Proposing a model of productized service life cycle model for medical devices
Time	March – September 2019
Method	Insider action research, semi-structured interviews
Case company description	Serres Oy, a Finnish manufacturer for operating theatre liquid management consumables and devices
Results	Thesis containing a review and a proposition on the goal subject, 69 pages, 6 appendixes
Main outcomes	Providing the case company with results, personal development of independent project work
Greatest challenges	Schedule fitting, different cultural practices, scientific research in private sector environment

A model for life cycle services considers the environment the product operates in *i.e.* hospitals. Medical devices are in contact with the patient directly or indirectly and affect their condition of health, thus the regulations and needs for safety and reliability as well as services are high. The model covers different levels of customer organization capabilities and needs through the life cycle. A product service-system life cycle contains a proposition different levels of subscription to a service from installation to replacement phases. There are basic needs of staff training, scheduled maintenance and defect maintenance with reactive, preventive and predictive aspects during its use, but also newer trends such as network connection and remote maintenance are proposed.

There are two main goals for a model of medical device productized services: to provide a new way of generating revenue; and to maximize safe medical device utilization in use environment. This model is functional in both categories.

6.2 Remarks on the research

The research in this thesis was conducted as a form of insider action research, which was a new method for the researcher. The method included interviews with semi-structured predetermined themes. Interviewing technical experts for a scientific publication was new for the researcher. In this light the research process from choosing the proper method all the way to executing it was successfully completed. There were research goals set in the beginning. Evaluating now afterwards these goals were reached. The process provided many lessons to learn such as communicational skills, notetaking, and drawing conclusions from a body of interviews. Greatest adversities were avoided, thanks to good guidance from faculty in form of master thesis seminar and an instructor as well as from the case company guiding group.

The greatest challenges during the research were timetables, different cultural practices and scientific research in private sector environment. Timetables in private sector summer vacations interrupted the whole thesis process, and when an interviewee was found, finding a common available slot turned out to be difficult. Different cultures in private sector and state-run entities, such as hospitals and universities, rose up as different practices. Some people prefer more formal communication and way of conducting communication and other prefer the efficient way. Additionally, the skills in English language in German organizations had more diversity than expected. When acquiring interviewees, some private sector workers seemed to have a disinterested approach to the scientific study. In a way this is understandable, as it might be experienced so that participating in a study is time directly out of their pocket. This might be the case in busy organizations.

The research itself has a form of uncertainty, as the number of interviews is not set with long experience in interview research and the researcher has only little experience in interview relevant skills. The interviewees are from niche fields of work, even though well informed for the case company agenda. There are some question marks if a control group or a second round of interviews would have strengthened the reliability of the thesis. Still, the theory of result saturation provides reliability in the research. It is certain that the increase in number of interviewees could have been greater. The researcher evaluated these aspects with the guiding group and thesis supervisors. Eventually it was seen that this thesis was conducted with honest intentions and according to the best abilities. The saturation of answers was derived to provide reliability. Nevertheless, the scope of the research in this thesis should be kept in mind when applying the results further.

6.3 Further application

The results of this thesis are well applicable in Finnish and German healthcare business environments. The results are suitable for the rest of western culture European countries with minor local modifications. In order to fully understand the service culture in a market area, it is highly recommended based on the experience in this thesis, to conduct market area research before applying the contents of this document. In hindsight, an interesting aspect for research would be the local regulations. There are multiple different aspects from infrastructure and plumbing to medical device regulation and certificates of operation in different countries that influence the use of a device.

Management of products and services need guidance tools in any given organization. For anyone using this thesis as a guiding piece of information, the role of this document should be strictly that of guiding. There are limiting aspects such as the number of interviews and areas of interviewee location. On the other hand, these interviewees truly are experts in their field of knowledge. Any decision should be accompanied with relevant knowledge and personal experience on the matter.

As the researcher of this thesis I would recommend continuing research and service development especially in serviceability and remote applications. Devices will have defects and especially after the launch, it is adamant to follow the typical service needs and to record the notes from maintenance crew performing the service. There most likely will be designed elements that cannot be foreseen to affect the serviceability of the device. Additionally, the service sector already has been applying the internet connection for its purposes for decades. This will be, and in some cases already is, the case in medical sector and will provide valuable and flexible info in the future. For future development, I strongly recommend researching the possibilities and requirements for online device defect diagnosis tools and the defect record prediction through defect or spare-part bundles. These bundles comprise of repairable and non-repairable systems or parts that are systematically tested via web-based tool.

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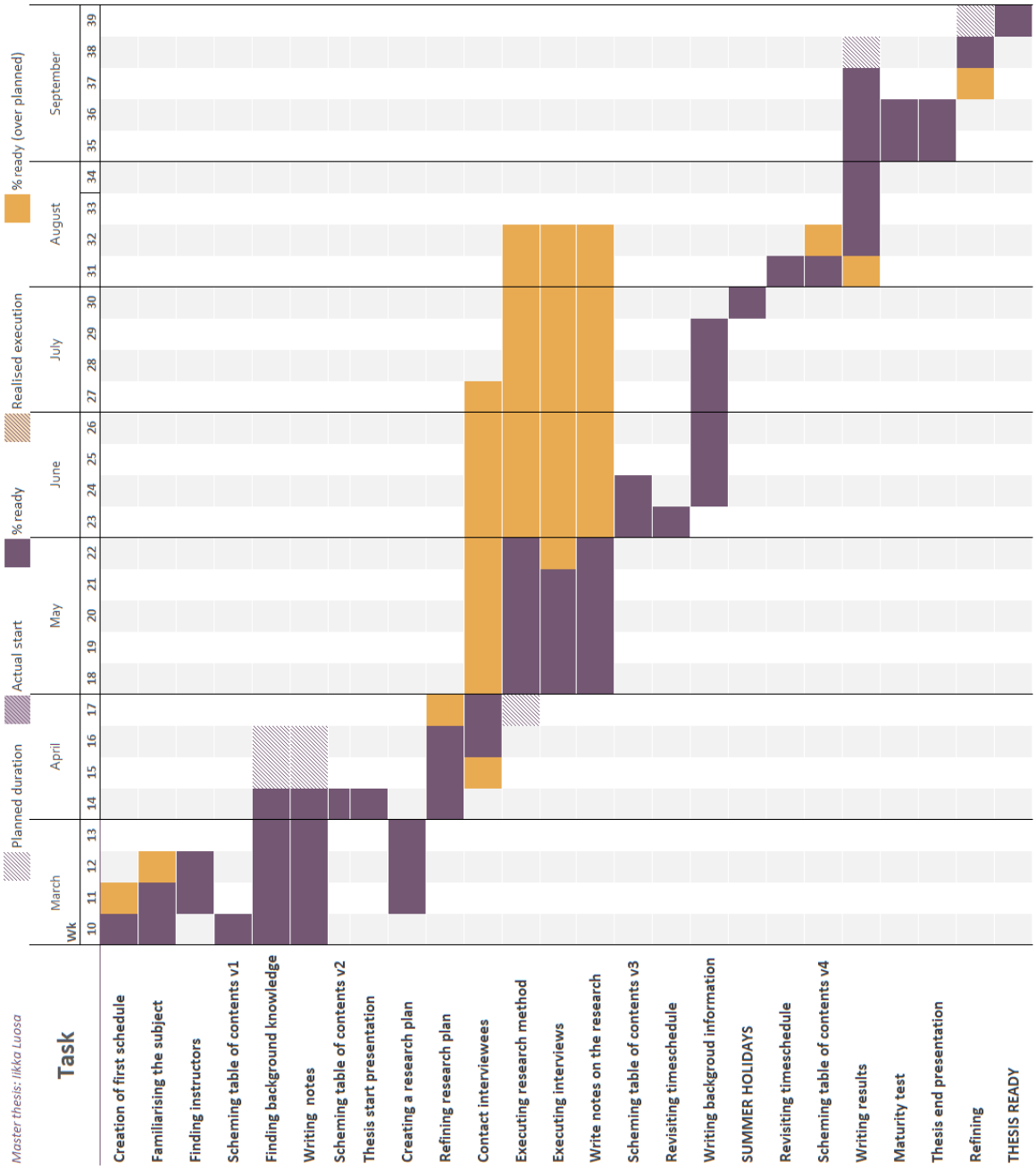
APPENDIX A: GANTT-FIGURE USED IN THE THESIS PROCESS



APPENDIX B – BASIC INTERVIEW STRUCTURE

Basic structure for an interview
REMEMBER TO RECORD!

DATE: PLACE:

NAME: ORGANISATION:

Introduction

Name, title, organization, brief intro to interviewees responsibilities

[Room for open questions & discussion]

Description of interviewees organization

Could you describe your team and your organization?
What services are you performing?
What services are outsourced?
What are the essential services you/your client needs?

[Room for open questions & discussion]

Basic services

What are the basic services for a device? What is done regularly?
What kind of services the end-users need from technical staff?
Could you describe your view on the medical device life cycle of services?
How do they see the future of medical device service?

[Room for open questions & discussion]

Serres product area

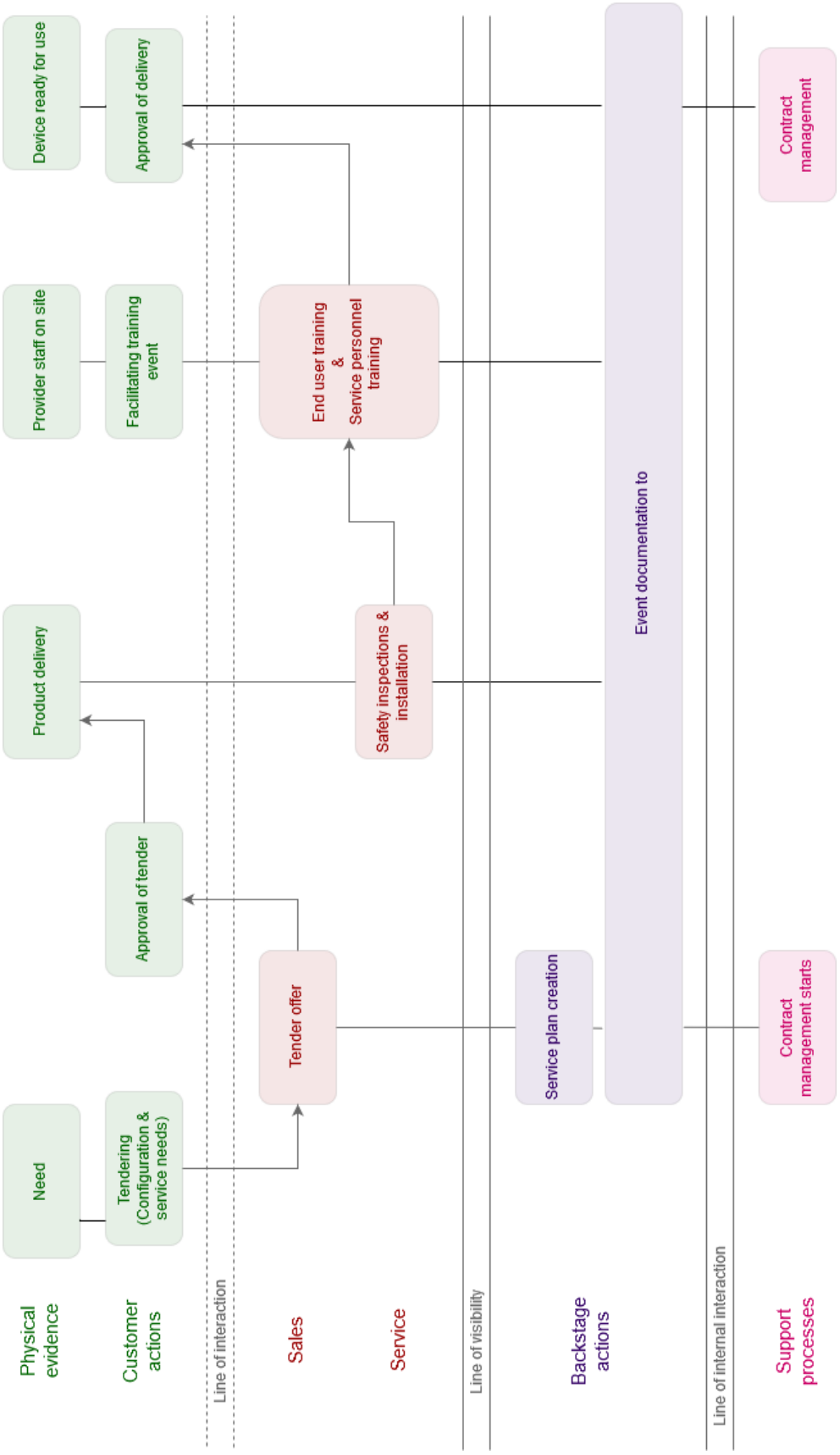
Are you aware of any suction products?
What kind of service is conducted to suction equipment?
Is there something jumping out related to suction equipment service?

[Room for open questions & discussion]

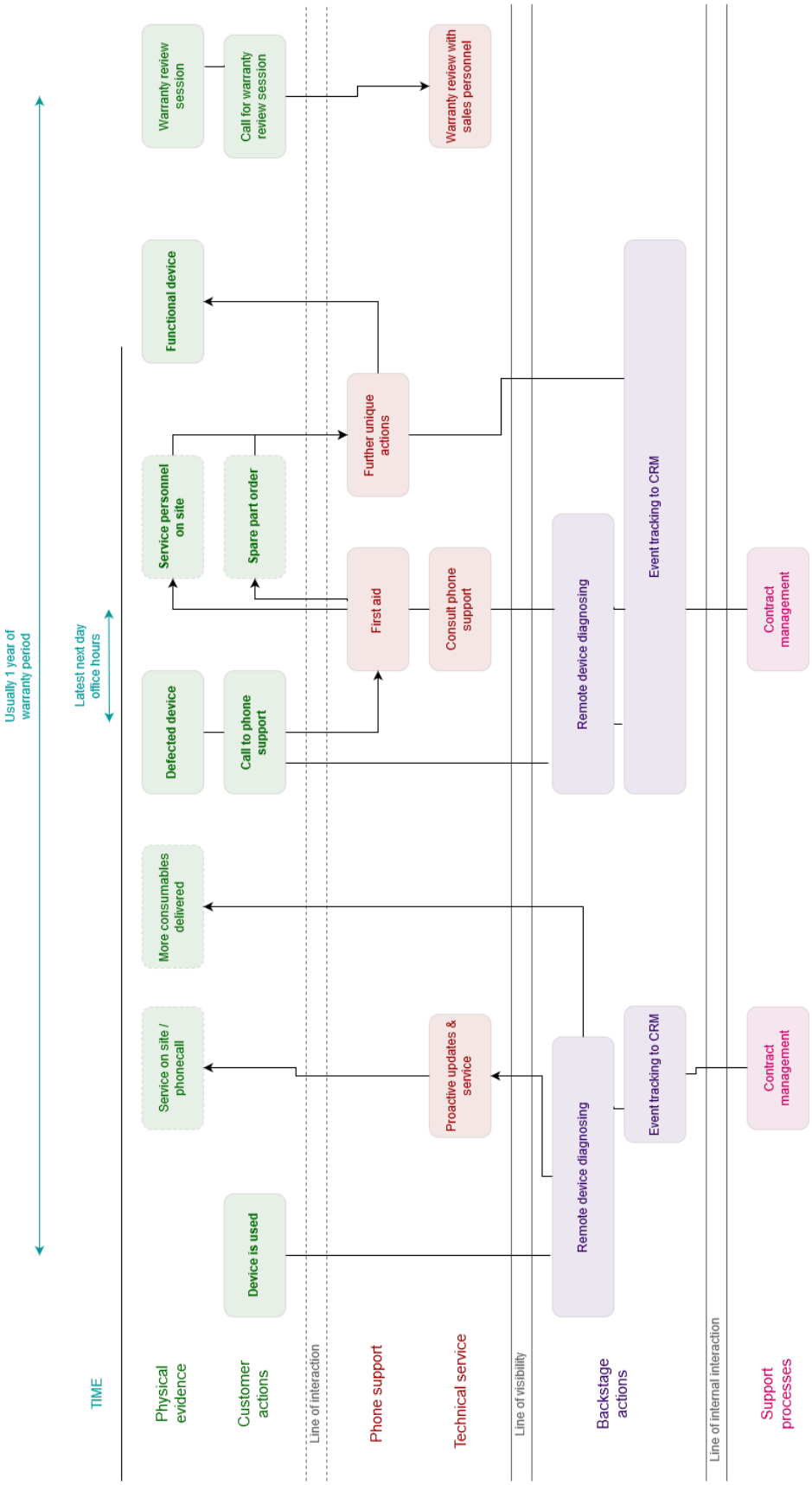
End

Is there something that was left out or still to discuss?
Thank you

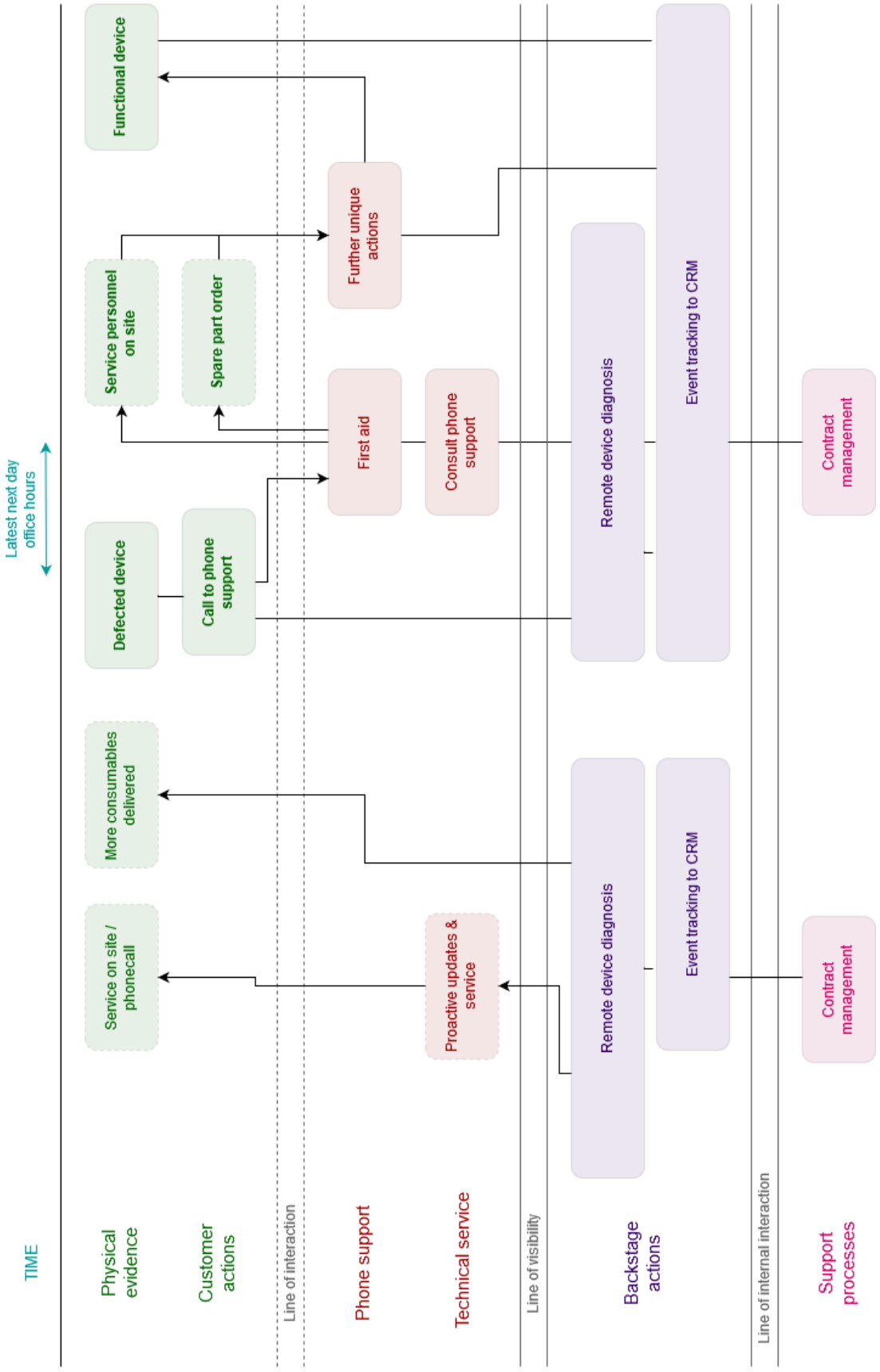
APPENDIX C: SERVICE BLUEPRINT - PREUSE



APPENDIX D: SERVICE BLUEPRINT - WARRANTY



APPENDIX E: SERVICE BLUEPRINT - USE



APPENDIX F: SERVICE BLUEPRINT - RECYCLING